EXHIBIT 12

Westlaw

Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2004 WL 422697 (N.D.Ill.), 70 U.S.P.Q.2d 1319
(Cite as: 2004 WL 422697 (N.D.Ill.))

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United States District Court,
N.D. Illinois, Eastern Division.
TAP PHARMACEUTICAL PRODUCTS, INC., Takeda Chemical Industries, Ltd. and Wako Pure Chemical Industries Ltd., Plaintiffs,
v.
ATRIX LABORATORIES, INC. and Sanofi-Synthelabo Inc., Defendants.
No. 03 C 7822.

March 3, 2004.

Kimball Richard Anderson, Raymond C. Perkins, Winston & Strawn LLP, Chicago, IL, William F. Cavanaugh, Jr., Jeffrey I.D. Lewis, Chad J. Peterman, Stuart E. Pollack, Patterson, Belknap, Webb & Tyler, New York, NY, for plaintiffs/counter-defendants.

Steven M. Evans, McGuireWoods LLP, Thomas R. Mulroy, Jr., Matthew T. Hurst, McGuireWoods LLP, Thomas Allen Marrinson, James M. Davis, Morgan Lewis Bockius, Chicago, IL, J. Eric Elliff, Morrison & Foerster, LLP, Denver, CO, Michael A. Jacobs, Morrison & Foerster, San Francisco, CA, Richard P. Pettus, Brian P. Murphy, Pamela C. White, Morgan, Lewis & Bockius, New York, NY, for defendants/counter-claimants.

MEMORANDUM OPINION AND ORDER

ZAGEL, J.

*1 On November 3, 2003, Plaintiffs Tap Pharmaceutical Products Inc. ("TAP"), Takeda Chemical Industries, Ltd. ("Takeda"), and Wako Pure Chemical Industries, Ltd. ("Wako") filed suit against Defendants Atrix Laboratories, Inc. ("Atrix") and Sanofi-Synthelabo, Inc. ("Sanofi") alleging infringement of United States Patent No. 4,728,721 ("721 patent"). [FN1] Prior to filing this suit, Plaintiffs successfully pursued a similar claim against Oakwood Laboratories, L.L.C. ("Oakwood") who have subsequently requested reexamination of the '721 patent by the Patent and Trademark Office ("PTO"). A second request for reexamination was made by an independent, undisclosed party. Both of these requests were granted before the instant suit was filed. Because of these two pending reexaminations, Defendants now move to stay these proceedings pending the resolution of the PTO's proceedings.

FN1. Takeda and Wako are joint owners of the '721 patent and TAP is their exclusive licencee.

Determining whether to grant a stay pending the outcome of the PTO's reexamination is a matter soundly within my discretion. *Gould v. Control Laser Corp.*, 705 F.2d 1340, 1341 (Fed.Cir.1983); *Emhart Industries, Inc. v. Sankyo Seiki MFG. Co., LTD.*, 3 U.S.P.Q.2d (BNA) 1889 (N.D.Ill.1987). When ruling on such a stay, courts have considered the following factors: (1) whether a stay will unduly prejudice or tactically disadvantage the non-moving party, (2) whether a stay will simplify the issues in question and streamline the trial, and (3) whether a stay will reduce the burden of litigation on the parties and on the court. *Wireless Spectrum Techs., Inc. v. Motorola Corp.*, 57 U.S.P.Q.2d (BNA) 1662, 1663 (N.D.Ill.2001). I find each of these factors weighs in favor of staying these proceedings.

1 Prejudice to the Plaintiff

Plaintiffs have known from the start of this case three months ago that the pending reexaminations could create grounds for a stay. As of yet, this case has not progressed beyond the initial pleadings stage; the parties have not engaged in any discovery and have not filed any other substantive motions. Since the litigation is at such an early stage and since Plaintiffs had notice of the pending reexaminations, I find they will not be unduly prejudiced by a stay. *See Wireless Specturm*, 57 U.S.P.Q.2d (BNA) at 1664; *Implant Innovations v. Noblpharma AB*, No. 93-C-7489, 1994 U.S. Dist. LEXIS 2033 at *9-10 (N.D.Ill. Feb. 24, 1994).

Plaintiffs argue that despite this, they still will suffer irreparable harm from the ensuing delay. Plaintiffs point out that the '721 patent may expire before the PTO's reexamination is completed, depriving them of any injunctive remedy. However, even if I deny the stay, the patent may still expire before a trial is completed. This is a large and likely complicated patent case with a potential damage award that could reach into the hundreds of millions of dollars (P. Resp. p. 12). In my experience, it is not unusual for such cases to remain in the pretrial stages for two to three years. [FN2] Alternatively, it is possible that the reexamination will simplify these proceedings and

ultimately make up for any delay that has been caused.

> FN2. The '721 patent is set to expire on May 1, 2006, a little more than two years from today's date.

*2 Next, the Plaintiffs argue that the delay will allow the alleged infringing product to gain market share, making damages greater and more difficult to collect. Given that A trix is a company with relatively few assets, Plaintiffs must have already considered the difficulties involved with enforcing a damages award against Sanofi, a French corporation. Any period of delay will not materially alter the need to pursue damages from Sanofi.

2 Simplification of the Issues

As the Federal Circuit has explained, "[o]ne purpose of the reexamination procedure is to eliminate trial of that issue (when the claim is canceled) or facilitate trial of that issue by providing the district court with the expert view of the PTO (when a claim survives the reexamination proceedings). *Gould*, 705 F.2d at 1342. The validity or invalidity of the '721 patent and its underlying claims is at issue both in this court and in the reexamination. Generally speaking, the PTO invalidates 10% of the patents it reexamines and amends the claims in 64%. If these proceedings are not stayed, there is a substantial risk of expending substantial resources on trying the validity of patent claims that may ultimately be cancelled or amended by the PTO. A stay will allow both the parties to take advantage of the PTO's expert analysis of prior art and may limit or narrow the remaining issues.

3 Reduction of the Burden Created by Litigation

There is a significant chance that the PTO will either invalidate this patent or drastically decrease its scope. This creates a very real possibility that the parties will waste their resources litigating over issues that will ultimately be rendered moot by the PTO's findings. Simplification of the issues will allow both parties to conserve time and resources. *Emhart*, 3 U.S.P.Q.2d (BNA) at 1890.

For these reasons, Defendants' Motion for Stay is GRANTED.

Not Reported in F.Supp.2d, 2004 WL 422697 (N.D Ill.), 70 U.S.P.Q.2d 1319

END OF DOCUMENT

EXHIBIT 13

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*1993 U.S. Dist. LEXIS 14601, **

TERADYNE, INC., Plaintiff, v HEWLETT-PACKARD COMPANY, Defendant.

No C-91-0344 MHP

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

1993 U.S. Dist. LEXIS 14601

January 7, 1993, Decided
January 7, 1993, Filed, Entered

CASE SUMMARY

PROCEDURAL POSTURE: Plaintiff filed an action charging defendant with patent infringement and defendant counterclaimed that plaintiff had infringed upon three of defendant's patents. Plaintiff sought summary judgment of one counterclaim and filed a motion for reconsideration of a temporary stay of the litigation of a second counterclaim, and defendant filed a motion to stay litigation of the remaining counterclaim pending a reexamination by the Patent Office.

OVERVIEW: The court determined that one of plaintiff's prior art references satisfied the literal terms of one claim of defendant's patent that was the subject of the summary judgment motion. Although defendant argued that the circuit tester's patent did not explicitly provide that a computer instruction was explicitly used to facilitate initialization and that deposition testimony could not be used to fill gaps in a patent claim's disclosure, the court found as a matter of law that initialization was covered by the claim in plaintiff's prior art and that the deposition testimony was uncontradicted that the tester's manual listed initialization as one of the iteration program's functions. The court determined that the litigation regarding defendant's remaining counterclaims should be stayed pending completion of the U.S. Patent Office's reexamination process. The court found that the reexamination might narrow or eliminate issues concerning the patents' validity and the reexamination process was intended for use in this situation where defendant discovered evidence of prior art during discovery that was not considered during the initial examination of the patent application.

OUTCOME: The court granted plaintiff's motion for summary judgment, denied plaintiff's motion for reconsideration of the temporary stay of litigation involving one of defendant's counterclaims, and granted defendant's motion for the stay of litigation regarding defendant's remaining counterclaim pending reexamination by the U.S. Patent Office.

CORE TERMS: patent, reexamination, signal, patent office, tester, predetermined, invalid, loop, cool-down, iteration, summary judgment, initialization, anticipated, discovery, testing, user, anticipation, in-circuit, time interval, variable, output, summary judgment motion, burst, specification, motion to stay, cool down, cycle, backdriving, overheating, invention

LexisNexis(R) Headnotes ♣ Hide Headnotes

Civil Procedure > Summary Judgment > Summary Judgment Standard

HN1 Under Fed. R. Civ. P. 56, summary judgment shall be granted against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial.

Civil Procedure > Summary Judgment > Burdens of Production & Proof

HN2 The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. The burden then shifts to the nonmoving party to go beyond the pleadings, and by its own affidavits, or by depositions, answers to interrogatories, or admissions on file designate specific facts showing that there is a genuine issue for trial.

Civil Procedure > Summary Judgment > Summary Judgment Standard

HN3 The court's function on a motion for summary judgment is not to make credibility determinations. The inferences to be drawn from the facts must be viewed in a light most favorable to the party opposing the motion.

Patent Law > Anticipation & Novelty > Elements
Patent Law > Infringement Actions > Summary Judgment > General Overview

HN4 Summary judgment is as appropriate in a patent case as in any other.

Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
Patent Law > Inequitable Conduct > General Overview

HN5 The proof of patent invalidity must be by clear and convincing evidence. Section 282 of the patent statutes, 35 U.S.C.S. § 282, explicitly provides for a presumption of patent validity. Section 282 places the initial burden of establishing a prima facie case on the party asserting invalidity; it also places the burden of persuasion on the challenging party throughout the litigation.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
Patent Law > Infringement Actions > Burdens of Proof

HN6 The presumption of validity exists because the patent office is presumed to have performed its job correctly. However, if the Patent Office did not consider the asserted prior art, such deference is not warranted. It is often difficult to discern whether a certain prior art was considered by the patent office. For instance, the failure of a patent examiner to cite a prior art is not conclusive evidence that it was not considered by the patent examiner. In addition, introduction of more pertinent prior art than that considered by the patent office does not shift the basic burden of persuasion from the patent challenger.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Claims & Specifications > Claim Language > Elements & Limitations
Patent Law > Anticipation & Novelty > Elements

HN7 A patent claim can only be invalidated on anticipation grounds if all elements and limitations of the claim are found in a single prior art reference.

Patent Law > Infringement Actions > Infringing Acts > General Overview
Patent Law > Infringement Actions > Claim Interpretation > General Overview

HN8 A finding of anticipation requires that all aspects of the claimed invention were already described in a single reference, a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decisionmaker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in gaps in the reference.

JUDGES: [*1] PATEL

OPINIONBY: MARILYN HALL PATEL

OPINION: MEMORANDUM AND ORDER

Plaintiff Teradyne, Inc. ("Teradyne") brought this action against defendant Hewlett-Packard ("HP") for allegedly infringing three of Teradyne's patents. HP brought a counterclaim against Teradyne for allegedly infringing five of HP's patents. The matter was last before the court on May 8, 1992 to consider Teradyne's summary judgment motion of invalidity for three of HP's patents, U.S. Patents Nos. 4,588,945 (" '945"); 4,642,561 (" '561"); and 4,598,245 (" '245"). At the hearing the court ordered that action on the '245 patent be stayed pending a reexamination by the Patent Office. The court ordered further briefing on the '561 patent and took the issue of the '945 patent under submission.

The matter is presently before the court on Teradyne's motion for reconsideration of this court's decision to temporarily stay litigation of the '245 patent and HP's motion to stay litigation of the '561 patent pending a reexamination by the Patent Office.

Having considered the submissions and arguments of the parties, and for the following reasons, the court GRANTS Teradyne's summary judgment motion with respect to claim 4 of the '945 patent. The [*2] court DENIES Teradyne's motion with respect to the other contested claims on the '945 patent. The court DENIES Teradyne's motion to reconsider the stay on the '245 patent. The court GRANTS HP's motion to stay litigation on the '561 patent.

I. BACKGROUND

A. Procedural History

On February 4, 1991 Teradyne filed its original Complaint, charging HP with infringing three of Teradyne's patents, U.S. Patents Nos. 31,828, 4,339,819, and 4,500,993. On June 28, 1991 HP filed an Amended Answer and Counterclaim, raising a number of defenses to the three Teradyne patents, and charging Teradyne with infringement of five of HP's patents, the three currently under review, '945, '561, '245, as well as U.S. Patents Nos. 4,040,025; and 4,652,814. Teradyne filed a reply and counterclaimed that each of HP's five patents-in-suit was invalid and not infringed.

On March 6, 1992 Teradyne filed three motions for summary judgment alleging that various claims of the '945, '561, and '245 patents were invalid as anticipated by the prior art under 35 U.S.C. § 102(b). Specifically, Teradyne sought a judgment that: (1) claims 1-5, and 7 of the '945 patent were invalid; [*3] (2) claim 1 of the '561 patent was invalid; and (3) claims 1-11 of the '245 patent were invalid. HP filed opposition to Teradyne's motions regarding the '945 and '561 patents, and sought to withdraw the '245 patent from this litigation, or in the alternative to stay litigation of the proceedings, because it was submitting the '245 patent for reexamination by the United States Patent and Trademark Office ("the Patent Office").

On May 6, 1992 HP filed a request for reexamination for the '245 patent in the Patent Office, pursuant to 35 U.S.C. § 301 et seq. On July 7, 1992, the Patent Office agreed to reconsider all claims of the '245 patent. Those proceedings are currently pending. At the May 8, 1992 hearing on Teradyne's summary judgment motions, this court stayed the proceedings with respect to the '245 patent pending the outcome of the Patent Office's reexamination of that patent. Teradyne now urges this court to reconsider the stay.

Regarding the '561 patent, the court heard several hours of oral argument concerning Teradyne's contention that claim 1 of the '561 patent was invalid. At the end of the hearing, the court ordered that supplemental [*4] evidence be obtained from GenRad, a firm which manufactured and marketed one of the test devices which Teradyne claimed was an anticipating prior art reference. After obtaining the supplemental GenRad witness's testimony, HP recognized that the test device raised new questions of patentability never considered by the Patent Office and accordingly, on July 6, 1992, submitted the '561 patent for reexamination. HP now requests a stay of the present action with respect to the '561 patent pending the outcome of the reexamination proceedings.

The court took Teradyne's summary judgment motion regarding the '945 patent under submission and that issue is presently ripe for summary adjudication.

B. Factual Background

HP's '945 patent relates to a relatively new method of testing PCBs, "in-circuit" testing, which tests the components that are mounted on a single PCB. n1 The circuit components are tested directly by applying test signals which have sufficient magnitude to overcome the effect of signals from other devices connected to the circuit component being tested. Joint Statement of Undisputed Facts Submitted with Teradyne's Motion for Partial Summary Judgment of Invalidity of Claims [*5] 1-5 and 7 of U.S. Patent 4,588, '945 ("JS '945") P 13. The tester applies appropriate signals to the input of the circuit component, monitors the output signals from the circuit component, and checks these output signals for accuracy.

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n1 Early generations of circuit testers for printed circuit boards (PCBs) used functional testing, in which test signals were applied only at circuit inputs and output signals were monitored only at circuit outputs. Functional testing suffered from two serious limitations. First, since each circuit was unique, it was difficult to determine the suitable test pattern for a specific circuit. Second, isolating a problem in the PCB required backtracking of the circuit and made diagnosis difficult. '651 Patent, col. 1, lines 18-28.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

To test a circuit component, a test signal pattern is applied. However, since circuit components are generally connected to other components, the application of a test signal pattern requires overcoming the effect of circuit components whose output signals constitute [*6] the input for the component under test. The process of overcoming the signals of these "upstream" components is known as "overdriving" or "backdriving." Id. Backdriving the output of upstream circuit components heats up the upstream components. '945 Patent, Col. 2, lines 1-28; col. 3, lines 3-43. Heating is particularly problematic since typical test signal patterns could include thousands of backdriving signals within a short period of time. In addition, since different circuit components that are tested typically have common upstream components which must be backdriven, such common components may never have the opportunity to cool down sufficiently so as not to become damaged.

Claims 1-5 and 7 of the HP's '945 patent involve methods for preventing thermal damage in conjunction with the use of a digital in-circuit tester. Claims 1 and 5 are independent claims. Claim 1 involves a method for introducing between test signals applied to circuit components a predetermined variable length cool-down time predetermined from characteristics of the circuit components under test and the overall characteristics of the circuit. The cool-down time is sufficient to avoid overheating of devices [*7] in the circuit. JS ' 945 P. 15. Claim 5 involves a means for applying the method of claim 1 in test signal use. Id.

Claims 2 and 3 depend on claim 1, while claim 7 depends on Claim 5. Claim 2 requires that the variable length cool-down time interval be determined by calculating the minimum time duration necessary to avoid damaging the device under test. Id. Claim 3 requires that the variable length cool-down time interval be introduced before application of the test signals to the component for which the time interval was determined. Id. Claim 7 involves a means for introducing the interval described by claim 3. Finally, independent claim 4 involves a method of preventing overheating when test signals are applied during initialization and during the regular period by terminating the application of test signals when a predetermined count has been reached or by limiting the length of the testing periods themselves. Id.

Teradyne asserts that claims 1-5 and claim 7 of the '945 patent are invalid because they were anticipated by three prior art references: (1) GenRad's 2270, 2271, and 2272 testers ("GR2270"); (2) Teradyne's L200 in-circuit tester [*8] ("L200"); (3) Schlumberger/Fairchild/Faultfinders' FF303/303S in-circuit testers ("FF303"). HP contends that the claims are not invalid because it invented a novel method of calculating a predetermined variable length cool down time interval based on the characteristics of the devices and the circuit. It asserts that although the prior art may have allowed for cool-down periods, these cool-down periods were set mechanically and were not related to the actual time period necessary to avoid damage.

II. DISCUSSION

A. The '945 Patent

1. Legal Standards

HN1 Under Federal Rule of Civil Procedure 56, summary judgment shall be granted:

> against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial . . . since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial.

Celotex Corp. v. Catrett, 477 U.S. 317, 322-23, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986); T.W. Elec. Serv. v. Pacific Elec. Contractors Ass'n, 809 F.2d 626, 630 (9th Cir. 1987). HN2 The [*9] moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. The burden then shifts to the nonmoving party to "go beyond the pleadings, and by [its] own affidavits, or by 'depositions, answers to interrogatories, or admissions on file' designate 'specific facts showing that there is a genuine issue for trial.'" Celotex, 477 U.S. at 324; see also Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986) (a dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.").

HN3 The court's function on a motion for summary judgment is not to make credibility determinations. Anderson, 477 U.S. at 249. The inferences to be drawn from the facts must be viewed in a light most favorable to the party opposing the motion. T.W. Elec. Serv., 809 F.2d at 631.

In its motion for summary judgment, Teradyne relies upon 35 U.S.C. § 102(b) which provides that a patent is invalid if "the invention was patented or described in a printed [*10] publication in this or a foreign country or in public use or sale in this country, more than one year prior to the date of the application for patent in the United States."

The federal circuit has repeatedly held that HN4 "summary judgment is as appropriate in a patent case as in any other." Avia Group Int'l, Inc.

v. L.A. Gear California, Inc., 853 F.2d 1557, 1561 (Fed. Cir. 1988) (citing cases). In addition, the federal circuit has upheld district court grants of summary judgment on the grounds of anticipation by prior art under 35 U.S.C. § 102(b). Constant v. Advanced Micro-Devices, 848 F.2d 1560, 1568-69 (Fed. Cir.), cert. denied, 488 U.S. 892, 102 L. Ed. 2d 218, 109 S. Ct. 228 (1988); Barmag Barmer Maschinenfabrik AG v. Murata Mach. Ltd., 731 F.2d 831 (Fed. Cir. 1984).

HN5 The proof of invalidity must be by clear and convincing evidence. RCA Corp. v. Applied Digital Data Systems, Inc., 730 F.2d 1440, 1444 (Fed. Cir.), cert. denied, 468 U.S. 1228 (1984). Section 282 of the patent statutes, 35 U.S.C. § 282, [*11] explicitly provides for a presumption of patent validity. Section 282 places the initial burden of establishing a prima facie case on the party asserting invalidity; it also places the burden of persuasion on the challenging party throughout the litigation. Lear Siegler Inc. v. Aeroquip Corp., 733 F.2d 881 (Fed. Cir. 1984).

HN6 The presumption of validity exists because the patent office is presumed to have performed its job correctly. American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359-60 (Fed. Cir.), cert. denied, 469 U.S. 821, 83 L. Ed. 2d 41, 105 S. Ct. 95 (1984). However, if the Patent Office did not consider the asserted prior art, such deference is not warranted. American Hoist, 725 F.2d at 1359. It is often difficult to discern whether a certain prior art was considered by the patent office. For instance, the failure of a patent examiner to cite a prior art is not conclusive evidence that it was not considered by the patent examiner. Lear Siegler, 733 F.2d at 885. In addition, introduction of more pertinent prior art than that considered [*12] by the patent office does not shift the basic burden of persuasion from the patent challenger. Id. (citing Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983)).

HN7 A patent claim can only be invalidated on anticipation grounds if all elements and limitations of the claim are found in a single prior art reference. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379 (Fed. Cir. 1986), cert. denied, 480 U.S. 947, 94 L. Ed. 2d 792, 107 S. Ct. 1606 (1987).

The so-called "doctrine of inherency" provides that the prior source need not expressly anticipate the claimed invention. Prior art can challenge a patent claim if it inherently possesses the patented property. See Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 633 (Fed. Cir.), cert. denied, 484 U.S. 827, 98 L. Ed. 2d 56, 108 S. Ct. 95 (1987). The existence of the inherent qualities of the prior art is sufficient; the inventor need not recognize these inherent qualities. Id. On the other hand, extrinsic evidence is of limited applicability in proving inherency. As the Federal Circuit noted in Scripps Clinic, 927 F.2d 1565 (Fed. Cir. 1991): [*13]

> HN8
> a finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decisionmaker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in gaps in the reference.

Id. at 1576 (citation omitted). In addition, inherency may not be established by possibilities or probabilities. The fact that a particular result may occur in a given set of circumstances is not sufficient to prove anticipation. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1269 (Fed. Cir.), reh'g denied, 1991 U.S. LEXIS 29979 (1991) (citing cases).

Finally, the question of anticipation also turns on claim interpretation. When dealing with anticipation, proper claim construction requires reference to both the specifications and to the prosecution history. See Lewmar Marine, Inc. v. Barient Inc., 827 F.2d 744, 750 (Fed. Cir. 1987), [*14] cert. denied, 484 U.S. 1007, 98 L. Ed. 2d 653, 108 S. Ct. 702 (1988); McGill v. John Zink Co., 736 F.2d 666, 673 (Fed. Cir.), cert. denied, 469 U.S. 1037, 83 L. Ed. 2d 404, 105 S. Ct. 514 (1984). The purpose of referring to the specification and prosecution history is to ascertain the scope and meaning of the claims. Id. However, extraneous limitation cannot be added to the claim through the use of specification language. Sjolund v. Musland, 847 F.2d 1573 (Fed. Cir. 1988).

With these standards in mind, the court considers Teradyne's summary judgment motion.

2. Only Claim 4 of the '945 Patent is Invalid as Anticipated By the Prior Art

Teradyne claims that claims 1-5 and claim 7 of the '945 patent are invalid because they were anticipated by three prior art references, GenRad's GR2270 in-circuit tester, Teradyne's L200 tester, and Schlumberger/Fairchild/Faultfinders' FF303 in-circuit testers.

a. The Three Prior Art References

The GR2270 in-circuit tester and user manual were commercially available more than a year prior to the grant of the '945 patent. JS ' 945 P 32 . The GR2270 had features [*15] which controlled the timing of test signals. One of the commands in the GR2270 test language was the BURST/END BURST command pair construct. The BURST command included the control parameter MAXTIME, which gave the user control of the maximum time that a burst test sequence could last. The user could specify 10, 40, 160 or 640 milliseconds. If no time was specified for MAXTIME, the GR2270 system would automatically select 640 milliseconds. Husser Dep. at 101:17-104:3. The test burst would be terminated when the actual elapse time reached the MAXTIME parameter. Id. 94:11-98:5. One of the purposes for the MAXTIME parameter was to

protect the circuit under test from overheating due to backdriving during the test period. Id. at 99:1-19.

The GR2270 system also included the LOOP/END LOOP instruction pair. Id. at 119:4-14. In the LOOP/ENDLOOP command pair, a loop count could be specified such that if a count were given, the loop would run until the count was met. If no count were given, the loop would run continuously until either a conditional exit condition was satisfied or the MAXTIME limit was reached. Id. at 108:10-110:4. [*16]

The L200 Board Test system was commercially available by 1981, more than a year before the grant of the '945 patent. Wrinn Dec. P 5. The L200 provided for a test language that contained instructions for generating loop sequences to repeat a set of test patterns. The L200 system incorporated a LOOP/ENDLOOP instruction pair construct, which terminated the loop when a user-specified maximum count was used. Wrinn Dec. PP 17-19; Hansen Dec., PP 3-5 and 7.

The FF303 existed more than one year before the filing of the HP '945 patent. Bish Dep. at 9:8-12. The FF303 had a CYCLE(N) command that was used for initializing sequential devices. The CYCLE command provided for a specified number of iterations N through the programmed test pattern for the cycle. The CYCLE command allowed test patterns for initializing a device to be repeated a specified number of times while looking for the starting state of the device before continuing on with the test. Id. at 56:13-60:9; 66:17-67:23.

The FF303 also provided for cool-down time between bursts of test patterns. A cool-down time was programmable by the user. If the user failed to program an inter-test time interval, the system would choose one automatically. [*17] Id. at 47:5-14; 50:25-51; 146:13-148:1. To adjust the cool-down time interval, a user would select a command called LDELAY. The user would specify the number of milliseconds that the tester should wait between each test sequence.

b. Claim 4 and the Prior Art References

Teradyne claims that every limitation of Claim 4 is met by each of the prior art references, the GR 2270, the L200, and the FF303. Claim 4 states:

> A method for preventing the overheating of an electronic device under test with initialization test signals during an initialization period or regular test signals during a testing period, the method comprising: counting the number of times the initialization test signals are applied to the electronic device under test, measuring the duration of the testing period, and terminating the application of test signals when a predetermined count or a predetermined period has been reached

Teradyne admits that of the three prior art references provided by Teradyne, only the GR2270 satisfies the literal terms of claim 4. GR2270 is the only one which sets time limits through iteration loops and time limits through predetermined periods. The other two references do [*18] not perform both limiting conditions. Teradyne argues, however, that the claim should be read in the alternative, to encompass any device which either sets time limits through iteration loops or sets time limits through predetermined periods. Teradyne's construction is clearly contrary to the plain language of claim 4, which says that the method must set time limits through a predetermined number of iterations and through a predetermined time period.

HP asserts that the GR2270 system does not anticipate Claim 4 of the '945 patent. According to HP, it is not clear whether the LOOP/ENDLOOP computer instruction was explicitly used to facilitate initialization. HP notes that GenRad's Dean Hussar merely stated that the instruction "could" be used to facilitate initialization of a circuit under test. Husser Dep. at 108:14-19.

However, in his deposition testimony, Husser repeatedly agreed that initialization testing was a valid use of the GR2270's iteration programming. Id. at 120:9-21; 121:21-122:9. Admittedly, as HP points out, Husser responded to some leading questions. HP also points out that Husser's extrinsic testimony cannot be used to fill in gaps in the GR2270 disclosure. [*19] However, Husser's testimony is corroborated by disclosure in the 1980 manual for the GR2270, which apparently listed initialization as one of the functions of the iteration programming. Id. at 120:3-8. HP does not argue that there was no such disclosure in the GR2270 manual.

HP also argues that particular specifications in the '945 patent militate against anticipation of claim 4 by the GR2270. In particular, HP contends that the tester of the '945 patent determines the exact number of iteration loops needed to initialize the circuit and exits the loop once this initialization is complete. '945 Patent, col. 7, lines 16-31. The GR2270, on the other hand, continues the iteration process until the number of iterations picked by the user is exhausted. However, reading this specification into claim 4 places an extraneous limitation on the claim which goes substantially beyond its plain language. HP's argument that the predetermined time and number of iterations selected by the tester needs to be related to the characteristics of the circuit also places extraneous limitations on claim 4. Unlike other claims made in connection with the '945 patent, claim 4 specifically does not [*20] discuss the tester's analysis of the characteristics of the circuit. In addition, contrary to HP's argument, there is no reason to believe that Claim 4 requires termination of all test signals once a predetermined count has been reached. For these reasons, the court finds that, as a matter of law, claim 4 of the '945 patent is invalid as being anticipated by a prior art.

c. Claims 1-3, 5 and 7 and the Prior Art

According to Teradyne, the FF303 anticipates claims 1 through 3, 5, and 7 of the '945 patent. Teradyne asserts that the FF303 provides for variable cool-down test intervals. In making this assertion, however, Teradyne completely ignores the fact that independent claims 1 and 5 of the '945 patent require a variable length cool down time interval that is predetermined from characteristics of the devices and the circuit. Teradyne makes no assertion that the FF303 makes any such calculation of cool down times. As independent claims 1 and 5 are not anticipated by the FF303, dependent claims 2-3 and 7 are likewise not anticipated.

B. Litigation Involving Both the '245 and the '561 Patents is Stayed Pending the Outcome of the Patent Office's Reexamination

As set [*21] forth above, Teradyne urges this court to reconsider its previous order staying the proceedings concerning the '245 patent to allow the Patent Office to reexamine all the patent's claims. Teradyne also opposes HP's motion to stay the '561 patent proceedings pending the outcome of reexamination. For the following reasons, Teradyne's efforts are unavailing.

This circuit has held that the district court has the authority to stay actions in order to:

> control the disposition of the cases on its docket in a manner which will promote economy of time and effort for itself, for counsel, and for litigants. The exertion of this power calls for the exercise of a sound discretion. Where it is proposed that a pending proceeding be stayed, the competing interests which will be affected by the granting or refusal to grant a stay must be weighed. Among these competing interests are the possible damage which may result from the granting of a stay, the hardship or inequity which a party may suffer in being required to go forward, and the orderly course of justice measured in terms of the simplifying or complicating of issues, proof, and questions of law which could be expected to result from a stay.

[*22]
Filtrol Corp. v. Kelleher, 467 F.2d 242, 244 (9th Cir. 1972), cert. denied, 409 U.S. 1110, 34 L. Ed. 2d 691, 93 S. Ct. 914 (1973) (citations omitted). n2

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n2 Teradyne's reliance on Wayne Automation Corp. v. R. A. Pearson Co., 782 F. Supp. 516 (E.D. Wash. 1991) for the proposition that the party requesting a stay must show that it would suffer hardship if the case were to go forward is not persuasive. In Wayne Automation the court refused to stay the litigation (with trial just six months away) because substantial discovery had already been completed and the stay request was the latest in a long series of the plaintiff's delaying tactics.

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These competing interests weigh in favor of staying the action and denying Teradyne's motion for reconsideration. The court's interest in efficiently managing its docket is served by a stay. Many, if not all, of the eleven challenged claims of the '245 patent and the single claim of the '561 patent may be modified or [*23] eliminated altogether during reexamination, thereby eliminating issues raised in Teradyne's motion for summary judgment. It has been estimated that in 77 percent of all reexamination applications, the claims are either amended or cancelled during reexamination. Output Technology Corp. v. Data Products Corp., 22 U.S.P.Q.2d (BNA) 1072, 1074 (W.D. Wash. 1991). Moreover, counsel for both parties have suggested that at least some of the claims will be amended during reexamination. See Reporter's Transcript of May 8, 1992 Hearing at 7-9. Since the reexamination process may narrow and perhaps eliminate issues concerning the patents' validity, the court should not expend unnecessary judicial resources by trying to resolve these claims now. See Gould v. Control Laser Corp., 705 F.2d 1340, 1342 (Fed. Cir.), cert. denied, 464 U.S. 935, 78 L. Ed. 2d 310, 104 S. Ct. 343 (1983) (purpose of the reexamination procedure is to eliminate the need for a trial if the claim is canceled or to provide the district court with the expert view of the Patent Office if the claim survives reexamination); Filtrol, 467 F.2d at 244 [*24] (noting that if the decision in the pending proceeding were to go against the party claiming the patent, a trial would not be necessary).

Congress has expressly stated that the reexamination process was intended for use in situations where a party discovers new evidence of prior art which was not considered during the initial examination of the patent application:

> The new procedure will permit any party to petition the patent office to review the efficacy of a patent, subsequent to its issuance, on the basis of new information about pre-existing technology which may have escaped review at the time of the initial examination of the patent application. Reexamination will permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation.

H.R. Rep. No. 1307, 96th Cong. 2d Sess. (1980). Early versions of what became the reexamination statute, 35 U.S.C. §§ 301-307, expressly provided for a stay of court proceedings during reexamination. See 35 U.S.C. § 310 (1979). When Congress amended the reexamination statute in 1981 it determined [*25] that an express provision was unnecessary. However, as explained in the House Report:

> The bill does not provide for a stay of court proceedings. It is believed by the committee that stay provisions are unnecessary in that such power already resides with the Court to prevent costly pretrial maneuvering which attempts to circumvent the reexamination procedure. It is anticipated that these measures provide a useful and necessary alternative for challengers and for patent owners to test the validity of the United States patents in an efficient and relatively inexpensive manner.

H.R. Rep. No. 1307 Part I, 96th Cong., 2d Sess. at 4 (1980), reprinted in 1980 U.S.C.C.A.N. 6460, 6463.

In accordance with clearly expressed congressional intent, district courts often stay patent proceedings pending reexamination. See, e.g., Ingro v. Tyco Industries, Inc., 227 U.S.P.Q. (BNA) 69, 71 (N.D. 111. 1985) ("legislative history indicates Congress . . . approved of courts liberally granting stays within their discretion "); Digital Magnetic Systems, Inc. v. Ansley, 213 U.S.P.Q. (BNA) 290 (W.D. Okla. 1982) ("Congress enacted the [*26] reexamination procedure to provide an inexpensive, expedient means of determining patent validity which, if available and practical, should be deferred to by the courts.").

Since a Patent Examiner who is familiar with the technology will conduct the reexamination, it is appropriate to stay the proceedings on the '245 and '561 patents so that the court can take advantage of the Patent Office's expertise. See Grayling Industries v. GPAC, Inc., 1991 U.S. Dist. LEXIS 16750, 19 U.S.P.Q.2d (BNA) 1872, 1873 (N.D. Ga. 1991); Brown v. Shimano American Corp., 18 U.S.P.Q.2d (BNA) 1496 (C.D. Cal. 1991).

Teradyne argues that it has conducted extensive discovery to prepare its summary judgment motions and would be prejudiced if the stay is left in place. Clearly, a party should not be allowed to use the reexamination procedure as delaying tactic after discovery and trial preparation are well under way. See Enprotech Corp. v. Autotech Corp., 1990 U.S. Dist. LEXIS 2926, 15 U.S.P.Q.2d (BNA) 1319 (N.D. Ill. 1990); E. I. Dupont de Nemours & Co. v. Phillips Petroleum Co., 711 F. Supp. 1205 (D. Del. 1989). In this case, however, the court's [*27] order staying litigation of the '245 patent was entered in May 1992, one month before the parties agreed on a discovery schedule. According to that schedule, discovery will last through November 1993, almost a year from now, and trial is set to begin in January 1994. Discovery concerning the '561 patent is governed by the same schedule. Accordingly, both the '245 and '561 patent proceedings are still in the initial stages of litigation and the reexamination procedure should be used. See Digital Magnetic Systems, 213 U.S.P.Q. at 290. n3

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n3 If the claims are invalid, the Patent Office will likely eliminate or amend them and Teradyne will suffer no prejudice at all.

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Finally, Teradyne contends that the stay will delay and disrupt efficient prosecution of this case. To the contrary, lifting the stay would compel the court to examine the validity of claims which are subject to modification during reexamination. As a result of the reexamination, the parties and the court may be required to [*28] revisit many of the same issues on a different record or the parties and the court may find they have engaged in this litigation effort for naught. Teradyne estimates that reexamination will take one year and be concluded by May 1993 for the '245 patent and July 1993 for the '561 patent. Therefore, the parties will have between four and six months after the Patent Office is finished reexamining the patents' claims to complete discovery. This leaves enough time for the parties to finish discovery and prepare for trial. If reexamination is protracted, the court can explore other avenues for proceeding on the remaining patents.

III. CONCLUSION

For the foregoing reasons it is HEREBY ORDERED THAT:

1. The court GRANTS plaintiff Teradyne's summary judgment motion with respect to claim 4 of the '945 patent.

2. The court DENIES Teradyne's motion with respect to the other contested claims on the '945 patent.

3. The court DENIES Teradyne's motion to reconsider the stay of the '245 patent.

4. The court GRANTS defendant Hewlett-Packard's motion to stay litigation of the '561 patent.

IT IS SO ORDERED.

Dated: January 7, 1993

MARILYN HALL PATEL

United States District Judge [*29]

EXHIBIT 14

SHEPARD'S®

*2002 U.S. Dist. LEXIS 9509, **

ROCKWOOD PIGMENTS, NA, INC , and CHEMISCHE WERKE BROCKHUES GmBH & Co. KG (f/k/a CHEMISCHE WERKE BROCHUES AG), Plaintiffs, vs. INTERSTATE MATERIALS, INC., Defendant.

No. 02 C 2178

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

2002 U.S. Dist. LEXIS 9509

May 28, 2002, Decided
May 29, 2002, Docketed

DISPOSITION: [*1] Defendant's motion for stay of litigation granted.

CASE SUMMARY

PROCEDURAL POSTURE: Defendant moved for a stay of plaintiff's patent infringement claim until the reexamination proceeding before the Patent and Trademark Office (PTO) was concluded.

OVERVIEW: Plaintiff was very confident in the outcome of the second reexamination proceeding, emphasizing that all claims were cancelled in only 12 percent of reexamination proceedings, giving an 88 percent clean bill of health, and claimed that it would be irreparably harmed if the stay was granted. The reference to an 88 percent clean bill of health was somewhat disingenuous, as plaintiff's data indicated that in third party requester reexaminations the claims were cancelled or at least changed 70 percent of the time. It was also disingenuous to characterize the result of the first reexamination proceeding as a clean bill of health. The second reexamination proceeding was well advanced, and plaintiff could use the stay as a reason for an expeditious ruling. Finally, if the claims were confirmed and it was determined that the patent was valid and defendant had infringed, defendant would be answerable in damages.

OUTCOME: Defendant's motion for a stay was granted.

CORE TERMS: reexamination, patent, examiner, clean, patentability, disingenuous, confirmed, cancelled

COUNSEL: For ROCKWOOD PIGMENTS NA, INC., CHEMISCHE WERKE BROCKHUES GMBH & CO. KG, plaintiffs: George Pellegrin McAndrews, Gregory Clements Schodde, Geoffrey Andrew Baker, Patricia Jane McGrath, Wilhelm L. Rao, McAndrews, Held & Malloy, P.C., Chicago, IL.

For INTERSTAR MATERIALS, INC., defendant: George S. Bosy, William P. Oberhardt, Harry J. Roper, Jonathan Hill, Roper & Quigg, Chicago, IL.

For INTERSTAR MATERIALS, INC., defendant: Jeffrey B Elikan, George F Pappas, Venable, Baetjer and Howard, LLP, Baltimore, MD

JUDGES: JAMES B. MORAN, Senior Judge, U. S. District Court

OPINIONBY: JAMES B. MORAN

OPINION: MEMORANDUM OPINION AND ORDER

The patent in this patent infringement case is before the Patent and Trademark Office (PTO) in reexamination proceedings. Defendant moves for a stay of this litigation until those proceedings are concluded. The stay is granted.

In a first reexamination proceeding the PTO examiner on March 16, 2001, determined that the "Beyn and Kneidinger alone or in view of the listed secondary references raises a substantial new question of patentability with respect to claims 1-11, which [*2] question has not been decided in a previous examination of the Jungk patent." That was followed on August 8, 2001, by a rejection of claims 1-11 (which are all the claims) "as being patentable over Beyn and Kneidinger et al alone or in view of McMahon, Feige et al., or Rodeffer." Plaintiff thereafter asserted that Kneidinger was not prior art, "which the examiner withdrew from consideration" and, on December 27, 2001, he confirmed the claims. The second reexamination proceeding followed, and it was determined on January 17, 2002, that "[a] substantial new question of patentability, affecting claims 1-11 ... is raised by the request for re-examination" and that Kneidinger "is available as prior art".

Plaintiff exudes confidence in the outcome of the second reexamination proceeding, emphasizes that all claims are cancelled in only 12 per cent of reexamination proceedings (an 88 per cent "clean bill of health" according to plaintiff), and contends that it will be irreparably harmed if the stay is granted. The reference to an 88 per cent clean bill of health is somewhat disingenuous, as plaintiff's data indicates that in third party requester reexaminations the claims are cancelled [*3] or at least changed 70 per cent of the time. More to the point, we are more concerned about what will happen here. It is also disingenuous to characterize the result of the first reexamination proceeding as a clean bill of health. With Kneidinger now available as prior art, the PTO examiner may well return to the position he took August 8, 2001. The second reexamination proceeding is well advanced, plaintiff can use this stay as a reason for an expeditious ruling; and if the claims are confirmed and it is determined that the patent is valid and defendant has infringed, defendant is answerable in damages.

JAMES B. MORAN

Senior Judge, U.S. District Court
May 28, 2002

EXHIBIT 15

Westlaw

Not Reported in F.Supp.
Not Reported in F.Supp., 1997 WL 94237 (D.Kan.)
(Cite as: 1997 WL 94237 (D.Kan.))

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Motions, Pleadings and Filings

Only the Westlaw citation is currently available.

United States District Court,
D. Kansas.
BRAINTREE LABORATORIES, INC., Plaintiff,
v.
NEPHRO-TECH, INC., et al., Defendants.
No. 96-2459-JWL.

Feb. 26, 1997.

Craig T. Kenworthy, Allen R. Slater, Swanson, Midgley, Gangwere, Kitchin & McLarney, L.L.C., Overland Park, KS, Arthur A. Smith, Jr., Roche, Carens & DeGiacomo, P.C., Boston, MA, for plaintiff.

Mark E. Brown, Litman, McMahon & Brown, Kansas City, MO, Steven H. Mustoe, Kurlbaum, Stoll, Seaman, Reefer Suter & Mustoe, P.C., Kansas City, MO, for defendants

MEMORANDUM AND ORDER

LUNGSTRUM, District Judge.

***1** This matter is presently before the court on defendants' motion to dismiss plaintiff's Lanham Act and common law unfair competition claims (Doc. 7) and defendants' motion to stay further judicial proceedings in this action (Doc. 9). The court concludes that plaintiff's Lanham Act and common law claims merely allege violations of the federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301-395, which does not allow for a private right of action; the court therefore grants the motion to dismiss Count II and Count III. The court also grants the motion to stay proceedings to allow reexamination of plaintiff's patent, the infringement of which plaintiff alleges in Count I of its complaint. [FN1]

FN1. The court concludes, in its discretion, that oral argument is not necessary with respect to these motions. See D. Kan. Rule 7.2.

I. Background [FN2]

FN2. The facts relevant to the motion to dismiss are derived solely from the complaint.

Plaintiff Braintree Laboratories, Inc. is a Massachusetts corporation. Plaintiff holds United States Patent No. 4,870,105, entitled "Phosphorous Binder", issued on September 26, 1989. According to plaintiff's complaint, the patent "claims methods, using calcium acetate, for inhibiting gastrointestinal absorption of phosphorous in an individual."

Plaintiff markets a drug called Phos-Lo, which implements plaintiff's patented method in the treatment of kidney dialysis patients, who have end-stage renal disease. The calcium acetate in the drug is intended to facilitate the excretion of phosphorous contained in food, a task normally performed by the kidneys. The federal Food and Drug Administration (FDA) approved plaintiff's drug on December 10, 1990, under the FDCA. The FDA also designated the drug an "orphan drug", i.e., a drug for a rare disease or condition, under 21 U.S.C. § 360bb and accompanying regulations, thereby precluding the FDA from approving similar drugs for a period of seven years.

Defendant Nephro-Tech, Inc. is a Kansas corporation, owned by defendants G.P. and Kimberly Georges. Defendants market a product called Calphron, which uses calcium acetate as a phosphorous binder. The FDA has not approved the product for marketing as a drug. Calphron is labeled as a "dietary supplement".

In Count I of its complaint, plaintiff alleges that defendants, by marketing Calphron, have infringed its patent, in violation of 35 U.S.C. § 271. On December 13, 1996, defendants filed a request for reexamination of plaintiff's patent by the United States Patent and Trademark Office (PTO), in accordance with 35 U.S.C. § § 301-307. Defendants have moved for a stay of judicial proceedings in this action to allow for the resolution of its request with the PTO.

In Count II, plaintiff alleges common law unfair competition by defendants. Specifically, plaintiff's complaint alleges as follows:

16. Defendants have violated the U S. Food, Drug and Cosmetic Act by introducing their drug, CALPHRON, into interstate commerce without submitting its [sic] product to the FDA for its required review authority and approval and without obtaining the statutorily required authority therefor and have, therefore, violated Plaintiff's property rights to seven years exclusivity under the Orphan Drug Act.

*2 17. Defendants have intentionally interfered with Plaintiff's contractual and business relations with doctors, patients and others by unlawfully supplying thereto said unauthorized drug in competition with Plaintiff and in violation of Plaintiff's seven-year market exclusivity.

18. Defendants' unlawful introduction of their unauthorized drug into interstate commerce constitutes unfair competition, defeats Plaintiff's entitlement to market exclusivity, damages the market for Plaintiff's patented invention and damages Plaintiff's ability to fairly compete, although it has the only legally required authorization.

In Count III, plaintiff alleges a violation of section 43(a) of the Lanham Act:

20. Defendants advertise their CALPHRON product as a "dietary supplement".

21. CALPHRON is not a dietary supplement, has not been so allowed by the FDA and such a claim misbrands the product.

22. Defendants, in connection with CALPHRON and/or containers for CALPHRON, are using in commerce false and misleading descriptions and representations of fact which are in commercial advertising and/or promotion and which misrepresent the nature, characteristics and qualities of their CALPHRON product all in violation of 15 U.S.C. 1125(a). Plaintiff is or is likely to be damaged by such acts.

II. Motion to Dismiss [FN3]

FN3. Both parties have included exhibits with their briefs. The court concludes that it is more appropriate in this instance to exclude those documents than to convert defendants' motion to one for summary judgment. *See* Fed.R.Civ.P. 8(b). Accordingly, the court has not considered the parties' submissions in resolving the motion.

A. *Standard*

A court may not dismiss a cause of action for failure to state a claim unless it appears beyond a doubt that the plaintiff can prove no set of facts in support of the theory of recovery that would entitle him or her to relief. *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957); *Jacobs, Visconsi & Jacobs, Co. v. City of Lawrence*, 927 F.2d 1111, 1115 (10th Cir.1991). The pleadings are liberally construed, and all reasonable inferences are viewed in favor of the plaintiff. Fed.R.Civ.P. 8(a); *Lafoy v. HMO Colorado*, 988 F.2d 97, 98 (10th Cir.1993). All well-pleaded facts, as distinguished from conclusory allegations, must be taken as true. *Jojola v. Chavez*, 55 F.3d 488, 494 n. 8 (10th Cir.1995) (citing *Swanson v. Bixler*, 750 F.2d 810, 813 (10th Cir.1984)). The issue in resolving a motion such as this is not whether the plaintiff will ultimately prevail, but whether he or she is entitled to offer evidence to support the claims. *Scheuer v. Rhodes*, 416 U.S. 232, 236, 94 S.Ct. 1683, 40 L.Ed.2d 90 (1974).

B. Count III--Lanham Act Claim

Plaintiff contends that the "dietary supplement" designation on defendants' product constitutes a false or misleading description in violation of section 43(a) of the Lanham Act. *See* 15 U.S.C. § 1125(a). [FN4] Defendants argue that this claim may not stand because it merely alleges a violation of the FDCA, for which no private right of action exists.

FN4. In its brief, plaintiff also suggests that defendants have violated the Lanham Act by including a National Drug Code listing number on their product and by promoting Calphron as an equal substitute for plaintiff's drug. Plaintiff has not sought to amend its complaint to include such claims, however. Thus, the court addresses the motion to dismiss within the contours of the original complaint.

The FDCA contains the following provision:

(a) Except as provided in subsection (b) of this section [relating to suits brought by states], all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.

*3 21 U.S.C. § 337(a). Although the Tenth Circuit has not considered the effect of section 337(a), every federal court that has addressed the question has held that the FDCA does not create a private right of action to enforce or restrain violations of its provisions. *Bailey v. Johnson*, 48 F.3d 965, 967 (6th

Cir.1995); *see PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105 (2d Cir.1997); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), cert. denied, 513 U.S. 965, 115 S.Ct. 429, 130 L.Ed.2d 342 (1994); *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130 (4th Cir.1993), *cert. denied*, 510 U.S. 1197, 114 S.Ct. 1307, 127 L.Ed.2d 658 (1994); *Pacific Trading Co. v. Wilson & Co.*, 547 F.2d 367 (7th Cir.1976) [FN5]

> FN5. In *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804, 106 S.Ct. 3229, 92 L.Ed.2d 650 (1986), the parties agreed with the lower court's ruling that no federal private cause of action existed for FDCA violations; the Supreme Court therefore assumed that ruling to be correct for purposes of its opinion and expressly refused to consider the question. *Id.* (holding that the presence of a violation of the FDCA as an element of a state cause of action was not sufficient to confer federal question jurisdiction).

It is significant that Congress, before passing the FDCA, "considered and rejected a version which would have allowed a private right of action for damages." *Bailey*, 48 F.3d at 968 (quoting *National Women's Health Network, Inc. v. A.H. Robins Co.*, 545 F.Supp. 1177, 1179 (D.Mass.1982)). If a private right of action were recognized, "the major advantages of enforcement through the [FDA] would be lost, including expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a unitary enforcement policy." *Id.* (quoting *National Women's Health Network*, 545 F.Supp. at 1180). The court concludes that the Tenth Circuit would agree with the analysis of its sibling circuits and hold that violations of the FDCA may not be alleged by private right of action.

Plaintiff does not bring its claims directly under the FDCA. Defendants argue, however, that plaintiff should not be allowed to use the Lanham Act or an unfair competition cause of action merely as a vehicle for the assertion of an FDCA violation. only a few cases have addressed this issue.

In *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir.1990), the plaintiff brought a Lanham Act claim, alleging that the defendant manufacturer falsely listed an ingredient as "inactive" on a cough syrup label when the FDA required that the ingredient be labeled as "active". *Id.* at 230. The defendant argued that the plaintiff had merely alleged a misbranding violation of the FDCA, for which there was no private right of action. *Id.*

The Third Circuit affirmed the district court's denial of a preliminary injunction, agreeing with the district court that the plaintiff had not shown a likelihood of success on the merits. *Id.* at 232. The court concluded that the plaintiff had not established that the labeling was false because the FDA had not found conclusively that the ingredient had to be labeled as "active" under its regulations. *Id.* at 230-31. The court stated:

> [The plaintiff's] position would require us to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations. Jurisdiction for the regulation of OTC drug marketing is vested jointly and exhaustively in the FDA and the FTC, and is divided between them by agreement. Neither of these agencies' constituent statutes creates an express or implied private right of action, and *what the [FDCA] and the FTC Act do not create directly, the Lanham Act does not create indirectly*, at least not in cases requiring original interpretation of these Acts or their accompanying regulations.

*4 *Id.* at 231 (emphasis added) (citations omitted). The Third Circuit concluded:

> As we have explained, the issue of whether an ingredient is properly labeled "active" or "inactive" under FDA standards is not properly decided as an original matter by a district court case.

Id. at 232.

The Fourth Circuit touched on the subject in *Mylan Labs. v. Matkari*, 7 F.3d 1130. There the Fourth Circuit reversed the dismissal of the plaintiff's claim that the defendants had falsely represented that their product was the "bioequivalent" of plaintiff's product; the court concluded that the plaintiff had pleaded facts sufficient to support that claim under the Lanham Act. *Id.* at 1138. The court, however, upheld the dismissal of the plaintiff's claim that the defendants had falsely represented that their drugs had been approved by the FDA. *Id.* at 1139. The court noted that the complaint did not point to any affirmative representation of FDA approval, and it held that such a "fatal deficiency" could not be cured by a contention that the very marketing of the drug implied such approval:

> Such a theory is, quite simply, too great a stretch under the Lanham Act. We agree with the defendants that permitting Mylan to proceed on the theory that the defendants violated § 43(a) merely by placing their drugs on the market would, in effect, permit Mylan to use the Lanham Act as a vehicle by which to enforce the Food, Drug, and

> Cosmetic Act ("FDCA") and the regulations promulgated thereunder. An attempt, by ingenious pleading, to escape one principle of law by making it appear that another not truly appropriate rule is applicable appears to have been attempted. *Mylan in short, is not empowered to enforce independently the FDCA.* In order to state a proper claim for relief under ... the Lanham Act, Mylan was required to point to *some* claim or representation that is reasonably clear form the fact of the defendants' advertising or package inserts. That it did not do.

Id. (first emphasis added) (citations omitted) (citing 21 U.S.C. § 337 and *Sandoz*, 902 F.2d at 230).

In *Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc.*, 720 F.Supp. 714 (N.D.Ill.1989), the court denied the defendants' motion to dismiss the plaintiff's Lanham Act claim. *Id.* at 716. In *Grove Fresh*, the plaintiff alleged that, because the defendants' product contained additives and adulterants, the representation that the product was "100% orange juice from concentrate" was false. *Id.* The defendants, in seeking dismissal of this claim, argued that the plaintiff was merely attempting to recover damages for a violation of the FDCA, which prohibits the misbranding of food. *Id.* The court concluded that the defendants had mischaracterized the nature of the plaintiff's claim:

> The fact that Grove Fresh refers to or relies on an FDA regulation defining orange juice to support its Lanham Act claim is not grounds for dismissal. Although courts have held that there is no private cause of action under the FDCA, Grove Fresh has not brought suit directly under the FDCA or its accompanying regulations. Grove Fresh relies on the FDA regulation merely to establish the standard or duty which defendants allegedly failed to meet. Nothing prohibits Grove Fresh from using the FDCA or its accompanying regulations in that fashion.
>
> *5 ... In the instant case ..., Grove Fresh does not base its claim solely on the FDCA or FDA regulations. Grove Fresh alleges that defendants have violated section 43(a) of the Lanham Act. Even without the FDA regulation defining "orange juice from concentrate," Grove Fresh could attempt to establish a violation of section 43(a). Grove Fresh would simply need to provide other evidence establishing the proper market definition of "orange juice from concentrate." Thus, Grove Fresh has asserted an independent basis for its claim ... which is sufficient to sustain its cause of action under Count I.

Id.; *See Genderm Corp. v. Biozone Labs.*, 1992 WL 220638 (N.D.Ill. Sept.3, 1992) (relying on *Grove Fresh* in determining that the plaintiff properly alleged a violation of the Lanham Act based on affirmative misrepresentations concerning the chemical make-up of certain ingredients).

In *Summit Technology, Inc. v. High-Line Medical Instruments Co. (Summit I)*, 922 F.Supp. 299 (C.D.Cal.1996), the plaintiff's Lanham Act claim concerned the defendants' failure to disclose that their ophthalmological laser systems had not been approved by the FDA. Id. at 306. The court concluded that the plaintiff's "false and misleading advertising allegations circumvent 21 U.S.C. § 337(a)'s denial of a private right of action to enforce violations of the FDCA." *Id.* The court noted that the FDA had not yet determined whether the defendants' systems needed approval, and it stated that allowing the plaintiff's Lanham Act claim would force the court to rule on the legality of the defendants' conduct before the FDA had had a chance to do so. *Id.* The court cited *Mylan* and *Sandoz*, and concluded that "[a]s such, this would use the Lanham Act as a vehicle for enforcing the requirements of the FDCA." *Id.* The court distinguished *Grove Fresh*:

> Furthermore, *Grove Fresh* involved the affirmative misrepresentation of a fact--the actual ingredients of the juice. Clearly, under both *Mylan* and *Grove Fresh*, a plaintiff may bring a Lanham Act cause of action for affirmatively misrepresenting facts, even if the truth of those facts may be governed by FDA regulations. By contrast, this case involves the failure to disclose a "fact," the truth of which is currently being reviewed and determined by the FDA.
>
> Therefore, because Plaintiff's Lanham Act action would essentially act as a private vehicle for enforcing FDCA and FDA regulations, it must be dismissed as to all Defendants.

Id. at 307 (citation omitted). The court also dismissed the plaintiff's statutory and common law unfair competition claims on this basis. *Id.* at 316.

The court had a chance to refine its analysis after the plaintiff amended its complaint. *See Summit Technology, Inc. v. High-Line Medical Instruments Co. (Summit II)*, 933 F.Supp. 918 (C.D.Cal.1996). The court in *Summit II* first reviewed its prior order, in which it held that "absent an affirmative misrepresentation that a drug had been officially approved by the FDA, a Lanham Act claim alleging that the defendant had failed to disclose FDA non-approval could not stand." *Id.* at 933. The court stated, however, that "false statements are actionable under the Lanham Act, even if their truth may be

generally within the purview of the FDA." *Id.* The court explained further in a footnote:

> *6 [A]n affirmative misrepresentation that a product has "FDA approval" ... is actionable because it clearly misstates a fact and does not require an interpretation or application of FDA regulations.... [A] court can test the truth of the statement "FDA approval" without any need to interpret FDA regulations. The question will simply be whether the FDA official conferred "approval" or not.

Id. at 933 n. 7.

The court then revisited the caselaw. The court noted that in *Mylan* the court had permitted the "bioequivalence" claim to proceed even though FDA regulations defined that term. *Id.* at 933 (citing *Mylan*, 7 F.3d at 1138). The court also noted that in *Grove Fresh*, the plaintiff's claim survived because, although FDA regulations defined "100% pure orange juice," the commercial definition could be determined "without performing an authoritative interpretation and direct application of FDA regulations." *Id.* (citing *Grove Fresh*, 720 F.Supp. at 715). *Sandoz*, on the other hand, involved a direct claim of misbranding, and "the matter in question was solely governed by an interpretation of FDA regulations." *Id.* at 933-34 (citing *Sandoz*, 902 F.2d at 231).

The court then considered specific representations by the defendants, which the plaintiff alleged to be false or misleading in violation of the Lanham Act. The court upheld Lanham Act claims based on representations involving whether the parties' lasers were "identical", whether the defendants' lasers had been approved by the FDA, and whether a defendant's machine was new. *Id.* at 935, 936, 940. Because the questions raised by those claims were factual and could be resolved without interpretation or application of FDA regulations, the court's inquiry did not "tread on the FDA's exclusive domain." *Id.* The court dismissed several other claims, however, based on representations involving descriptions of FDA policy and whether the FDA permitted certain importation, use, and repair of the defendants' lasers. *Id.* at 935-42. Such statements were more "nebulous" than affirmative statements of non-approval, and consideration of those statements would have required original interpretation and application of the FDCA and the regulations. *Id.* Finally, the court concluded that the plaintiff could not bring an unfair competition claim that was, in fact, an attempt to state a claim under the FDCA. *Id.* at 943 n. 21.

A general framework may be gleaned from these cases. It is clear that a plaintiff may not maintain a Lanham Act claim alleging only that the defendant has failed to disclose that the FDA has not approved its product. Affirmative misrepresentations, however, are generally actionable under the Lanham Act, even if the product is regulated by the FDA. Most obviously, a false statement of FDA approval is actionable. It is also clear that, because no private right of action exists under the FDCA, a plaintiff may not use the Lanham Act as an alternative vehicle by which to seek redress for an FDCA violation. Moreover, claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA, especially in light of Congress's intention to repose in that body the task of enforcing the FDCA. The court believes that the Tenth Circuit would embrace these general principles.

*7 Here plaintiff has alleged that defendants have affirmatively represented that Calphron is a "dietary supplement." That term is defined in the FDCA. *See* 21 U.S.C. § 321(ff). Defendants thus argue that plaintiff has merely alleged a misbranding violation and that such claim may not be brought because it requires application and interpretation of the FDCA definition.

Plaintiff argues that this case should be decided like *Grove Fresh*. Plaintiff contends that, like the plaintiff in *Grove Fresh*, it relies on the statutory definition only to provide a standard, which defendants failed to meet. *See* 720 F.Supp. at 716. Plaintiff argues that it has asserted an independent basis for its claim because it could establish a misrepresentation even without the FDCA definition. For instance, according to plaintiff, Calphron is not a "dietary supplement" in the ordinary sense because the calcium in the product is not intended to be absorbed.

The court concludes, however, that the present case is more analogous to *Sandoz*. There the court held that the issue of whether an ingredient was "active" or "inactive" under the regulations was more properly resolved by the FDA. 902 F.2d at 232. Similarly, it is not for this court to interpret and apply the statutory definition of "dietary supplement". In particular, the court notes that, under the FDCA, a product is misbranded if it is a "dietary supplement" under the FDCA and that term is not used on its label. 21 U.S.C. 343(s). Thus, even if it were determined in litigation that Calphron did not meet

some independent, lay understanding of the term "dietary supplement", defendants might not be able to remove the term from its label without violating the FDCA and risking a suit by the FDA. The possibility of such a dilemma demands that classic misbranding claims, such as the one here at issue, be reserved solely for resolution by the FDA. [FN6] Therefore, under the principles set forth above, plaintiff cannot maintain its Lanham Act claim, and defendants' motion to dismiss that claim is granted.

> FN6. The court addressed such a problem in *Summit II*. There the plaintiff alleged that a defendant had advertised a "custom" laser developed by the defendant, when it was actually an altered laser manufactured by the plaintiff. 933 F.Supp. at 941. The court allowed the claim, even though the FDCA defined "custom". Id. at 941. The court concluded that the claim was "purely and unmistakably" one for "reverse palming off," specifically actionable under the Lanham Act; thus, the plaintiff could attempt to establish that the defendant was passing the laser off as his own without reference to the FDCA definition. *Id.* at 941, 941 n. 18. The court noted that the defendant could avoid a "Catch-22" situation by continuing the "custom" designation but making the laser's origin clear. *Id.* at 941 n. 18.
> The instant situation is distinguishable. Here, plaintiff's claim, as alleged by the complaint, does not focus on Calphron's efficacy as a calcium supplement; plaintiff does not point to any other means, other than by use of the FDCA-required term "dietary supplement", by which defendants have allegedly attempted to mislead the consumer in this way. In fact, given plaintiff's allegation that defendants are invading the renal disease community with its own phosphorous binder, it is probable that the other representations on Calphron's label explain the product's intended effect. While in *Summit II*, the plaintiff's claim was, in essence, a Lanham Act claim, plaintiff's claim in the instant case is, at its heart, a misbranding claim, as evidenced by plaintiff's use of the statutory term "misbrand" in the complaint.

C. *Count II--Common Law Claim*

The same concerns that militate against allowing the Lanham Act to serve as a vehicle for alleging FDCA violations attend the use of a common law cause of action. Therefore, the same general principles discussed above govern plaintiff's common law unfair competition claim. *See Summit II*, 933 F.Supp. at 943 n. 21; *Summit I*, 922 F.Supp. at 316; *National Women's Health Network*, 545 F.Supp. at 1181 ("A private right of action is equally inconsistent with the federal regulatory scheme, whether the right is based in federal or state law."). [FN7]

> FN7. Thus, in this context of a claim by a competitor, the personal injury cases cited by plaintiff, in which a violation of the FDCA served as one element of a state cause of action, are inapposite.

In Count II of its complaint, plaintiff alleges that defendants have violated the FDCA by introducing Calphron into the market without seeking FDA approval and that such "unlawful introduction of their unauthorized drug into interstate commerce constitutes unfair competition, defeats Plaintiff's entitlement to market exclusivity," and causes damages. The crux of this count is defendants' failure to receive FDA approval under the FDCA. Thus, plaintiff's claim is unmistakably one for direct enforcement of the FDCA, for which no private right of action exists, either under that statute or the common law.

*8 In its brief, plaintiff argues that it is attempting by this claim to vindicate a property right, namely, its seven-year exclusivity with respect to its "orphan drug". Even if the court were to interpret Count II of plaintiff's complaint to assert such a claim independent of the non-approval charge previously discussed, such claim would fail. The FDCA does not speak of "exclusive rights"; it merely provides that if the FDA approves a drug and designates it an "orphan drug", it may not approve another such drug for seven years. 21 U.S.C. § 360cc(a). Plaintiff cannot support a direct violation of the exclusivity provision because plaintiff has not alleged that the FDA wrongfully approved Calphron. Even if the statute created some sort of property interest, plaintiff, in asserting a violation of that interest by defendants, would have to show that Calphron is a "drug" and therefore' subject to the provision. Such a claim would require direct interpretation and application of the FDCA and therefore may not be brought by private civil action. Finally, plaintiff has not cited to any cases recognizing the "orphan drug" exclusivity as a property right, the violation of which

by a competitor would be actionable. [FN8]

> FN8. The court may not consider the unpublished case cited by plaintiff in its brief because plaintiff failed to attach a copy of that opinion for the benefit of the court. *See* D. Kan. Rule 7.6(b).

Accordingly, the court grants defendants' motion to dismiss Count II of the complaint.

III. Motion to Stay

Defendants have also moved for a stay of judicial proceedings pending the PTO's consideration of defendants' request for reexamination of plaintiff's patent. Under the relevant statute, any person may file a request for reexamination of a patent by the PTO based on prior art. 35 U.S.C. § § 301, 302. Within three months, the PTO must decide whether reexamination is warranted. *Id.* § 303. If the request is granted, reexamination proceedings are then conducted "with special dispatch." *Id.* § 305. After reexamination, the original patent claim may be limited or amended to distinguish it from the prior art. *Id.* § § 305, 307.

"A motion to stay an action pending the resolution of a related matter in the United States Patent and Trademark Office is directed to the sound discretion of the court." *Rosenthal Mfg. Co. v. Thermal Equip., Inc.*, 1988 WL 383034, at *1 (D.Kan. Oct.12, 1988). Here, the court concludes that the benefits of a stay outweigh any prejudice to plaintiff; accordingly, the court exercises its discretion and grants plaintiff's motion for a stay.

The Federal Circuit Court of Appeals considered such a stay in *Gould v. Control Laser Corp.*, 705 F.2d 1340 (Fed.Cir.), cert. denied, 464 U.S. 935, 104 S.Ct. 343, 78 L.Ed.2d 310 (1983). The court first noted the requirement that reexamination proceedings be conducted with "special dispatch." *Id.* at 1341 (quoting 35 U.S.C. § 305). The court then pointed to the following statutory goal:

> One purpose of the reexamination procedure is to eliminate trial of that issue (when the claim is canceled) or to facilitate trial of that issue by providing the district court with the expert view of the

***9** PTO (when a claim survives the reexamination proceeding) *Id.* at 1342. The court also noted that although early versions of the reexamination statute expressly provided for a stay of judicial proceedings, such provision was deemed unnecessary, as explained in the following excerpt from a House report:

> The bill does not provide for a stay of court proceedings. It is believed by the committee that stay provisions are unnecessary in that such power already resides with the Court to prevent costly pretrial maneuvering which attempts to circumvent the reexamination procedure. It is anticipated that these measures provide a useful and necessary alternative for challengers and for patent owners to test the validity of United States patents in an efficient and relatively inexpensive manner.

Id. (quoting H.R.Rep. No. 1307, 96th Cong., 2d Sess. 4 (1980), *reprinted in* 1980 U.S.S.C.A.N. 6460, 6463). The court concluded:

> When a district court stays patent validity proceedings before it until completion of a reexamination proceeding, that stay must be accepted if the purpose of the reexamination statute is to be preserved.

Id.

The Federal Circuit has noted that the benefits of the reexamination procedure, as revealed by the statute's legislative history, include settling patent validity disputes more quickly and less expensively than often-protracted litigation and allowing courts to rely on the PTO's expertise. *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 602 (Fed.Cir.1985). The Federal Circuit has also cautioned that courts and the PTO apply different standards and may therefore reach opposite results. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed.Cir.1988).

"It is clear from the cases ... that there is a liberal policy in favor of granting motions to stay proceedings pending the outcome of USPTO's reexamination or reissuance proceedings." *ASCII Corp. v. STD Entertainment USA*, 844 F.Supp. 1378, 1381 (N.D.Cal.1994). Courts have cited a number of advantages to allowing reexamination before litigation:

1. All prior art presented to the Court will have been first considered by the PTO, with its particular expertise.
2. Many discovery problems relating to prior art can be alleviated by the PTO examination.
3. In those cases resulting in effective invalidity of the patent, the suit will likely be dismissed.
4. The outcome of the reexamination may encourage a settlement without the further use of the Court.
5. The record of reexamination would likely be entered at trial, thereby reducing the complexity

and length of the litigation.
6. Issues, defenses, and evidence will be more easily limited in pre-trial conferences after a reexamination.
7. The cost will likely be reduced both for the parties and the Court.

Fisher Controls Co. v. Control Components, Inc., 443 F.Supp. 581, 582 (S.D.Iowa 1977); *accord GPAC, Inc. v. D.W.W. Enters.*, 144 F.R.D. 60, 63 (D.N.J.1992); *Robert H. Harris Co. v. Metal Mfg. Co.*, 19 U.S.P.Q.2d 1786, 1789 (E.D.Ark.1991); *Emhart Indus. v. Sankyo Seiki Mfg. Co.*, 3 U.S.P.Q.2d 1889, 1890 (N.D.Ill.1987); *United Merchants & Mfrs. v. Henderson*, 495 F.Supp. 444, 447 (N.D.Ga.1980). A stay would confer these advantages in this case.

***10** Courts have denied stays where undue prejudice would result or one party would suffer a clear tactical disadvantage; for instance, a stay may not be appropriate if discovery has been completed or the case is otherwise in a late stage. *GPAC*, 144 F.R.D. at 63-64. Such concerns are not present here, however, as this case is only a few months old.

Plaintiff argues that it would suffer irreparable harm from a stay because its seven-year period of exclusivity terminates in December of 1997. As defendants note, however, any such harm results not from a stay, but rather from defendants' marketing activities, which presumably would continue during any stay. Plaintiff's concern would more appropriately have been raised in support of a request for a preliminary injunction against defendants' selling its product during the pendency of this litigation; plaintiff did not seek such relief, however. Moreover, even without a stay, it is not likely that this litigation would be completed by December.

The court thus concludes that a stay is appropriate in this case, and it grants defendants' motion.

IT IS THEREFORE ORDERED BY THE COURT THAT defendants' motion to dismiss Count II and Count III is granted.

IT IS FURTHER ORDERED BY THE COURT THAT defendants' motion to stay these proceedings for reexamination of plaintiff's patent is granted.

IT IS SO ORDERED.

Not Reported in F Supp., 1997 WL 94237 (D.Kan.)

Motions, Pleadings and Filings **(Back to top)**

- 2:96cv02459 (Docket) (Oct. 18, 1996)

END OF DOCUMENT

EXHIBIT 16

Westlaw

Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2004 WL 1968669 (S.D.Iowa)
(Cite as: 2004 WL 1968669 (S.D.Iowa))

Motions, Pleadings and Filings

Only the Westlaw citation is currently available.

United States District Court,
S.D. Iowa, Central Division.
MIDDLETON, INC., Plaintiff,
v.
MINNESOTA MINING AND MANUFACTURING COMPANY, Defendant.
No. 4:03-CV-40493.

Aug. 24, 2004.

Donald William Rupert, Mayer Brown Rowe & Maw LLP, Joseph A. Grear, George C. Summerfield, Keith A. Vogt, Stadheim & Grear, Jonathan G. Bunge, Bunge Law Firm PC, Chicago, IL, Suzanne J. Levitt, Des Moines, IA, for Plaintiff and Counter-Defendant.

Daniel L. Hartnett, Crary Huff Inkster Hecht & Sheehan PC, Soux City, IA, David M. Swinton, Ahlers & Cooney PC, Des Moines, IA, William A. Streff, Jr., David Kenneth Callahan, Mary E. Zaug, Karen J. Nelson, Kirkland & Ellis LLP, Chicago, IL, Kevin H. Rhodes, 3M Innovative Properties Company, St. Paul, MN, for Defendant and Counter-Claimant.

ORDER GRANTING DEFENDANT'S MOTION TO STAY

GRITZNER, J.

***1** This matter is before the Court on Defendant's Motion to Stay (Clerk's No. 170). Defendant brought the motion as a result of a recently granted reexamination [FN1] of the patent-in-suit by the Patent and Trademark Office ("PTO"). Based on Defendant's request for expedited relief, an oral hearing was held on Friday, August 13, 2004, via telephone. Attorney George C. Summerfield appeared on behalf of the Plaintiff; attorneys David Callahan and Karen Nelson appeared on behalf of the Defendant. Following the hearing, the Court took the matter under advisement and finds Defendant's motion is now fully submitted and ready for ruling.

FN1. While the PTO officially granted an *inter partes* reexamination, counsel for Defendant noted at the hearing that this was clerical error, and the PTO is in the process of rectifying the mistake. The reexamination must necessarily be *ex parte* due to the age of the patent at issue. This change has no effect on the parties' arguments or the Court's analysis of the motion to stay.

PROCEDURAL HISTORY AND BACKGROUND FACTS

The Plaintiff, Middleton, Inc. ("Middleton"), commenced this action against the Defendant, Minnesota Mining and Manufacturing Co. ("3M"), in the United States District Court for the Northern District of Illinois, Chicago Division, on October 17, 1996. After much litigation activity in that district, the Honorable James F. Holderman of the Northern District of Illinois transferred the action to this Court on August 29, 2003. Jurisdiction is proper pursuant to 28 U.S.C. § 1331, the federal question statute, and 28 U.S.C. § 1338(a), as this case arises under the federal patent laws, 35 U.S.C. § § 101 et seq.

The lawsuit alleges infringement of a patent held by Middleton, specifically, U.S. Patent No. 4,944,514 ("the '514 patent"), by 3M. Trial is scheduled for the week beginning October 12, 2004. The Court also has three summary judgment motions pending. The first motion was filed by Middleton and pertains to infringement. The second and third motions, filed by 3M, pertain to validity and infringement, respectively. 3M filed an application for reexamination [FN2] and learned on July 26, 2004, that the PTO had granted the request. The pending reexamination prompted the current motion to stay, which Middleton has resisted.

FN2. Out of courtesy, 3M made the Court aware of its pending application for reexamination. While the PTO was making its decision, the present action moved forward in accordance with the scheduling order.

ANALYSIS

3M has moved to stay this matter based on the PTO's granted reexamination of the patent-in-suit. This case has a long and convoluted history even before the present circumstances giving rise to this motion.

Prior to even coming to rest before this Court, this action proceeded from the United States District Court for the Northern District of Illinois to the Federal Circuit and back multiple times. Now, the present motion comes after eight years of litigation and with just over two months remaining before trial. Middleton resists the motion based primarily on the short time left before trial and the delay in seeking reexamination. Middleton also contends 3M lacks the authority to even bring the pending motion.

Briefly, the PTO recently granted [FN3] 3M's request for reexamination of the '514 Patent based on the determination that the multiple independent prior art references identified by 3M in its application "raised substantial new questions of the patentability of claims 4-7," the patent claims at issue in the present infringement action. [FN4] Based upon this determination, 3M contends "[i]t is now highly likely that the PTO will either declare these claims of [the '514 Patent] invalid, or require Middleton to narrow the claims to avoid the prior art references." *See Tap Pharm. Prods., Inc. v. Atrix Labs., Inc.*, 2004 WL 422697, at *2 (N.D.Ill. March 4, 2004) ("There is a significant chance that the PTO will either invalidate this patent or drastically decrease its scope."). [FN5] 3M contends the result of the reexamination could end or dramatically impact the remaining issues in this case, especially considering the PTO found all 13 references cited in the reexamination patent, either alone or in combination, relevant to patentability. Therefore, 3M requests the Court stay all proceedings in this case pending the outcome of the reexamination by the PTO. Specifically, 3M argues the stay should be granted because this will allow for the most efficient use of the Court's resources, it will simplify the issues for trial, and it will not unduly prejudice Middleton.

FN3. The determination was mailed by the PTO on July 19, 2004, and received by 3M on July 26, 2004.

FN4. The prior art references identified by 3M consist of the following: U.S. Patent No. 3,785,102 ("Amos"); U.S. Patent No. 4,151,319 ("Sackoff"); U.S. Patent No. 4,543,765 ("Barrett"); U.S. Patent No. 4,328,274 ("Tarbutton"); Russian Patent Publication SU 1,111,880 ("Shevchenko"); U.S. Patent No. 3,665,543 ("Nappi"); Japanese Patent Document Sho 61-98834 ("Shirasu"); Unexamined German Patent Application Number 1,809,794 ("Wilson"); U.S. Patent No. 3,788,941 ("Kupits"); U.S. Patent No. 2,987,103 ("Yakubik"); U.S. Patent No. 4,221,620 ("Milne"); U.S. Patent No. 4,095,340 ("Kingsley"); and U.S. Patent No. 4,115,917 ("Charon").

FN5. "Generally speaking, the PTO invalidates 10% of the patents it reexamines and amends the claims in 64%." *Tap Pharm. Prods., Inc.*, 2004 WL 422697, at *2.

A. Statutory Authority to Request a Stay

*2 Middleton first argues that 3M lacks the statutory authority to request a stay. Middleton bases this assertion on an examination of the statues governing patent reexamination. Pursuant to section 318 of the Patent Statute,

> Once an order for *inter partes* reexamination of a patent has been issued under section 313, *the patent owner* may obtain a stay of any pending litigation which involves an issue of patentability of any claims of the patent which are the subject of the *inter partes* reexamination order, unless the court before which such litigation is pending determines that a stay would not serve the interests of justice.

35 U.S.C. § 318 (emphasis added).

Middleton claims this section clearly limits the rights set forth to those of the patent owner. In contrast, section 311 of the Patent Statute provides that *"[a]ny person* at anytime may file a request for *inter partes* reexamination...." 35 U.S.C. § 311(a) (emphasis added). When Congress uses different terms in a statute, the presumption is that those terms have different meanings. *See Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 497, 112 S.Ct. 2589, 120 L.Ed.2d 379 (1992). Therefore, according to Middleton, while "any person" may file an *inter partes* reexamination request, only "the patent owner" may seek a stay of litigation once such a request is granted.

Further, courts generally refer to Federal Rule of Civil Procedure 1 ("Rule 1"), allowing for "the just, speedy, and inexpensive determination of every action," when reciting their authority to grant a stay of proceedings. *See, e.g., W. Tenn. Chapter of Associated Builders & Contractors, Inc. v. City of Memphis*, 138 F.Supp.2d 1015, 1029 (W.D.Tenn.2000). Regulations cannot, however, trump the plain language of conflicting statutes. *Ellis v. General Motors Acceptance Corp.*, 160 F.3d 703, 709 (11th Cir.1998) (quoting *Robbins v. Bentsen*, 41 F.3d 1195, 1198 (7th Cir.1994)); *see also Caldera v.*

J.S. Alberici Constr. Co., 153 F.3d 1381, 1383 n.* * (Fed.Cir.1998) (finding that "[s]tatutes trump conflicting regulations") Because the relevant statute provides that "the patent owner" can ask for a stay in the event of an *inter partes* reexamination, Middleton contends that Rule 1 does not give the Court the broader authority to grant such a request by 3M, which is not the patent owner.

This contention is easily resolved as Middleton disregards the Court's inherent discretionary power to issue a stay. *See Softview Computer Prods. Corp. v. Haworth, Inc.*, 2000 WL 1134471, at *2 (S.D.N.Y. Aug.10, 2000) (finding "there is no question that a district court in which an infringement action has been filed has the discretion to stay the infringement action pending the outcome of the reexamination proceeding") (citing *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27 (Fed.Cir.1988)); *see also Robert H. Harris Co. v. Metal Mfg. Co.*, 1991 WL 217666, at *3 (E.D.Ark. June 21, 1991) ("Whether the action should be stayed pending the outcome of the reexamination proceeding before the PTO resides in the discretion of the court."). The Court has this discretion even though the reexamination procedure does not expressly provide for an automatic stay of parallel district court proceedings. *Softview Computer Prods. Corp.*, 2000 WL 1134471, at *2 (citations omitted); *see also Grayling Indus., Inc. v. GPAC, Inc.*, 1991 WL 236196, at *1 (N.D.Ga. March 25, 1991) ("The decision whether to stay proceedings in district court while a reexamination by the PTO takes place, while not vested expressly in the discretion of the district court by the statute, has been recognized to be within the district court's inherent discretionary power.").

**3 As the courts have recognized, "Congress stated its approval of district courts liberally granting stays within their discretion" when the committee stated " '[i]t is believed by the committee that *stay provisions are unnecessary in that such power already resides with the Court* ...' " *Emhart Indus., Inc. v. Sankyo Seiki Mfg. Co.*, 1987 WL 6314, at *2 (quoting H.R.Rep. No. 1307 Part I, 96th Cong., 2d Sess. 4, *reprinted in* 1980 U.S.Code Cong. & Ad. News 6460, 6463 (emphasis added)); *see also Fisher Controls Co. v. Control Components Inc.*, 443 F.Supp. 581, 581 (S.D.Iowa 1977) ("The district court's power to stay proceedings has been drawn purposefully broad and is discretionary.") Indeed, "[c]ourts have routinely stayed infringement actions pending the outcome of reexamination proceedings," *Softview Computer Prods. Corp.*, 2000 WL 1134471, at *2 (citations omitted), and Middleton has cited to no authority supporting the limitation it asserts. Accordingly, this Court finds it has the authority to issue a stay in the present matter if the circumstances weigh in favor of staying the proceedings. *See Gould v. Control Laser Corp.*, 705 F.2d 1340, 1341-42 (Fed.Cir.1983) [FN6]

> FN6. In addition, as noted in footnote 1, this is an *ex parte* reexamination, while the statutes relied on by Middleton in raising this argument apply to *inter partes* reexaminations.

B. Standard for Motion to Stay

Generally, courts consider the following factors in determining whether to grant a stay: "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set." *Softview Computer Prods. Corp.*, 2000 WL 1134471, at *2-3 (quoting *Xerox Corp. v. 3Com Corp.*, 69 F.Supp.2d 404, 406 (W.D.N.Y.1999) (citations omitted)). In other words, based on these factors the Court determines whether the benefits of a stay outweigh the associated costs.

The advantages that may result from a stay of the district court proceedings pending completion of reexamination by the PTO include,

> "1. All prior art presented to the Court will have been first considered by the PTO, with its particular expertise.
> 2. Many discovery problems relating to prior art can be alleviated by the PTO examination.
> 3. In those cases resulting in effective invalidity of the patent, the suit will likely be dismissed.
> 4. The outcome of the reexamination may encourage a settlement without the further use of the Court.
> 5. The record of reexamination would likely be entered at trial, thereby reducing the complexity and length of the litigation.
> 6. Issues, defenses, and evidence will be more easily limited in pretrial conferences after a reexamination.
> 7. The cost will likely be reduced both for the parties and the Court."

Emhart Indus., Inc., 1987 WL 6314, at *2 (quoting *Fisher Controls Co.*, 443 F.Supp. at 582 (S.D.Iowa 1977)). [FN7] Reexamination may result in the elimination of most, if not all, of the issues remaining in the pending litigation. *See Gould*, 705 F.2d at

1342. If not found invalid, the reexamination will at least likely result in a narrowing and simplifying of the issues before the Court. [FN8] *See Loffland Bros. Co. v. Mid-Western Energy Corp.*, 1985 WL 1483, at *2 (W.D.Okla. Jan.3, 1985). In addition, the technical expertise provided by the reexamination proceeding will be helpful to the Court on any issues that remain. *See Gould*, 705 F.2d at 1342.

> FN7. "Although not binding on the Court, the PTO's determination will be admissible and will carry a presumption of validity." *Ralph Gonnocci Revocable Living Trust v. Three M Tool & Mach. Co.*, 68 U.S.P.Q.2d 1755, 1759 (E.D.Mich.2003).
>
> FN8. This is because the scope of the patent claims, which the PTO may narrow or otherwise limit, controls the outcome of any subsequent infringement analysis. *See Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1344 (Fed.Cir.2002) (finding "an assessment of whether an accused device infringes claims of a patent necessarily involves both an identification and interpretation of the asserted claims, and a comparison of the properly interpreted claim limitations to the elements of the accused device").

*4 Plaintiff makes three primary arguments against issuance of a stay. First, Middleton argues the issuance of a stay will not promote judicial economy. Second, Middleton urges the Court to deny the stay based on 3M's delay in filing for reexamination. Third, Middleton contends it will be prejudiced if the stay is granted. In the alternative, if the Court determines a stay is warranted, Middleton requests the Court grant a stay only as to those issues before the PTO. Each of these contentions is summarized and discussed below.

1. Judicial Economy

Both parties accept that one factor in determining the propriety of a stay of proceedings in the face of reexamination is the judicial economy that such stay would promote. Middleton contends that, contrary to 3M's assertions, a stay would not promote judicial economy at all in this case because of the amount of preparation by the parties thus far. This matter has now been pending for eight years, and that fact alone would seem to argue strongly against a stay. However, despite the lengthy pendency of this matter in the Northern District of Illinois, the validity of the '514 patent has only been explored by the parties for a little over a year, in isolation hardly an unusual period of time for development of such issues.

According to Middleton, the court in *Toro Co. v. L.R. Nelson Corp.* ruled a stay was unwarranted under similar circumstances.

> This suit has been pending in litigation for almost 3 1/2 years. Before the motion for stay was filed, the court had under advisement a motion by defendant for summary judgment, which may well be dispositive of the issue of validity of asserted claims 14 and 15. Those factors militate against a stay at this stage of the proceedings.
>
> The pendency of this suit does not necessarily preclude any further proceedings which the Patent Office may choose to pursue. It is the opinion of the court that its granting of a stay order would accomplish little, other than the delay of disposition of a suit which has, until now, run an overly protracted course.

Toro Co. v. L.R. Nelson Corp., 223 U.S.P.Q. 636, 638 (C.D.Ill.1984).

Middleton contends that the factual circumstances impacting judicial economy in *Toro* and in the present case are vastly different than those involved in the cases cited by 3M. *See Tap Pharm. Prods., Inc.*, 2004 WL 422697, at *1 ("Plaintiffs have known from the start of this case three months ago that the pending reexaminations could create grounds for a stay. As of yet, this case has not progressed beyond the initial pleadings stage; the parties have not engaged in any discovery and have not filed any other substantive motions."); *Ralph Gonnocci Revocable Living Trust*, 68 U.S.P.Q.2d at 1758 ("This action has been pending for less than a year. Undoubtably the parties have spent considerable time and resources thus far--substantial discovery has been conducted and the parties have submitted witness lists and three lengthy summary judgment motions. Yet far more time and resources remain to be spent before this matter is concluded. Two responses to motions for summary judgment must be submitted, the Court has not begun to review those motions, and much remains to be done by the parties and the Court to prepare this case for trial."); *Softview Computer Prods. Corp.*, 2000 WL 1134471, at *3 ("[A]lthough there has been a great deal of activity in this litigation to date, much remains to be done before the case is ready for trial. Discovery is not yet completed, extremely voluminous summary judgment motions have been served, the *Markman* hearing has not yet been held and the Pretrial Order has not yet been prepared."); *Robert H. Harris Co., Inc.*, 1991 WL

217666, at *4 ("[T]his action has been pending less than a year. Although it is set for trial next month, the Court is not persuaded that this a case which has 'run an overly protracted course' ... The parties appear not to have engaged in expensive discovery or extensive pretrial preparation") (citations omitted); *Emhart Indus., Inc.*, 1987 WL 6314, at *3 (noting that "substantially no trial preparations have been carried out--there is no pretrial order in place and no trial schedule has been set"). Arguably, none of these cases was at the stage of litigation that the present case indicates.

*5 In the present action, all summary judgment motions have been fully briefed, and discovery appears essentially complete. Accordingly, Middleton claims a stay at this point would do little to serve the interests of judicial economy, and would only have the effect of further delaying final resolution of this matter, which has already been pending far too long.

Additionally, Middleton contends 3M's reliance in part on *Standard Havens Products, Inc. v. Gencor Industries, Inc.* is misplaced as Middleton does not base its opposition to the present motion to stay on the proposition found to be faulty. *See Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 996 F.2d 1236, 1993 WL 172432, at *1 (Fed.Cir. May 21, 1993) (reversing the lower court's decision denying a stay, as such decision was based upon the obviously incorrect proposition that a "reexamination decision can have no effect on this infringement suit even if the reexamination decision becomes final."). [FN9]

FN9. Middleton also notes that this decision is unreported and, as such, "shall not be employed as precedent by this court, and may not be cited by counsel, except in support of a claim of res judicata, collateral estoppel, or law of the case." Fed. Cir. R. 47.8. However, the decision is relevant not as precedent but to demonstrate the final result of issues similar to those in the present case.

At least one court found the fact that discovery is complete and the case set for trial has been found to be the most compelling reason to justify denial of a motion to stay pending reexamination by the PTO. *See Enprotech Corp. v. Autotech Corp.*, 1990 WL 37217, at *1-2 (N.D.Ill. March 16, 1990) (finding these factors the most compelling and concluding the action was "too far along the road to justify halting the journey while the defendant explores an alternate route" in denying the motion to stay). Likewise, this is the most compelling argument made by Middleton in resisting the pending motion to stay.

In the present case, the litigation has been ongoing for over eight years. [FN10] The trial date is set and is scheduled for the week of October 12, 2004. In addition, several motions for summary judgment remain pending that may be dispositive of some or all of the issues remaining in the case. Discovery is completed, and the parties are most likely well into their trial preparation. Thus, the parties have already spent a considerable amount of time and money on the pending litigation. On its face, these facts seem to weigh against granting a stay.

FN10. As indicated in the text, most of the history of this case occurred in the Northern District of Illinois and the Federal Circuit through litigation activities promoted by both parties. The issue now before the Court is of much more recent vintage.

However, these facts should be weighed against the benefits of issuing a stay. As argued by 3M, the following factors weigh in favor of issuing a stay: (1) a stay will be the most efficient use of judicial resources by preventing duplication of effort; (2) the reexamination may simplify and narrow the issues in the case; and (3) the Court will be able to benefit from the expertise of the PTO. Moreover, a stay issued pending reexamination "is not for such a protracted or indefinite period" as reexamination proceedings are to " 'be conducted with special dispatch.' " [FN11] *Gould*, 705 F.2d at 1341 (quoting 35 U.S.C. § 305). Thus, while some courts have denied a stay based on the end of discovery and the proximity of trial, *see Toro Co.*, 223 U.S.P.Q. at 638; *Enprotech Corp.*, 1990 WL 37217, at *2, the ultimate determination is within the Court's discretion based on a weighing of the benefits of issuing a stay versus any added expenses resulting from the stay.

FN11. One study listed the average pendency of a reexamination to be 19 months. *See* Note, "Reexamination Reality: How Courts Should Approach a Motion to Stay Litigation Pending the Outcome of Reexamination", 66 Geo. Wash. L.Rev. 172, 192 app. A (Nov.1997). This note is, however, over seven years old, and the parties were unable to indicate to the Court whether this estimate is accurate, though Defendant's counsel thought, but could not state definitively, that the average pendency

has been shortened.

*6 In the present action, the Court finds the element of judicial economy does in fact weigh in favor of granting the motion to stay. First, a stay would preserve the costs of a trial on the merits that may be obviated by the results of the reexamination. Second, even if a trial is ultimately required, the Court can have all issues heard in one trial on the proper scope of the patent claims. In addition to limiting the issues at trial, the reexamination decision may also limit the issues in the currently pending dispositive motions. Finally, the Court will be able to use the expertise of the PTO in making further determinations as related to the proper patent claims. In that regard, the Court is influenced by the breadth of the reexamination and the number of prior art references under active review.

The Court acknowledges the considerable expense already endured by the parties in the present action but notes that these costs will not be recouped by denying a stay and proceeding to a trial. This may actually compound the parties' expenses if some or all of the issues need to be retried later as a result of the reexamination. In addition, the Court disagrees with Middleton's contention that only incremental resources will be expended if the action proceeds to trial. It is simply not efficient to rule on three motions for summary judgment, complete pretrial, and hold a full jury trial if all or part have to be redone. The apparent scope of the reexamination, the technical expertise of the PTO, and the relationship to the issues in this case suggest to the Court a great likelihood that the continuing work of this Court would be impacted by the reexamination. The judicial efforts that a stay would preserve outweigh any additional cost in staying the proceedings even at this late juncture.

C. Filing for Reexamination

Middleton also argues that 3M's delay in filing reexamination warrants denying the motion. As noted above, 3M did not seek reexamination of the patent-in-suit until well after the commencement of the litigation. In addition, one of the references upon which 3M relied in seeking reexamination was one of its own patents. Under these circumstances, Middleton contends that it is an inevitable conclusion that 3M delayed unduly in seeking reexamination [FN12]

FN12. Middleton avers this is not the first time that 3M has used the reexamination procedure to engage in delay. For proof, Middleton cites to the decision in *Freeman v. Minnesota Mining & Mfg. Co.*, in which the court, apparently anticipating a motion to stay from 3M, had the following to say:
Though not before the Court, it seems worthwhile to state the Court's view on granting a stay of court proceedings pending the PTO reexamination. In *Digital Magnetic*, the court commented that 'parties should not be permitted to abuse the [reexamination] process by applying for reexamination after protracted, expensive discovery or trial preparation.' ... Discovery was concluded in this case seven months ago, and the first of the two suits was filed two and a half years ago. Moreover, 3M knew about all three of the documents on which its reexamination petition will be based no later than August 8, 1986. To allow 3M to now use the reexamination process to get this case stayed would be to allow a defendant to use the reexamination as a mere dilatory tactic.
Freeman v. Minnesota Mining & Mfg. Co., 661 F.Supp. 886, 888 (D.Del.1987) (citations omitted). However, 3M's actions in another case are not relevant to the present action, especially considering the court's statement in *Freeman* was *anticipatory* and not in reaction to any actual motion to stay filed by 3M, let alone any proof that 3M was so moving for the purpose of delaying or unduly protracting the litigation. 3M's motion in the present case will be analyzed on its own merits and under the circumstances of the present action.

Courts have generally considered a delay in seeking reexamination in evaluating the propriety of a stay in light of such reexamination. Indeed, "[t]he potential for abuse inherent in granting a stay where the petition for reexamination comes very late and without explanation is apparent." *Grayling Indus., Inc.*, 1991 WL 236196, at *2. For example, in *Enprotech Corp.*, the defendant first raised the question of reexamination and an associated stay some 18 months after the commencement of litigation and four months before trial. *Enprotech Corp.*, 1990 WL 37217, at *1. That court, in denying the motion to stay, stated "[w]e are too far along the road to justify halting the journey while the defendant explores an alternate route." *Id.* at *2; *see also Toro Co.*, 223 U.S.P.Q. at 638 (denying stay given three

and a half year delay)

*7 Middleton asserts again that the authority cited by 3M in support of granting a stay is inapposite on this issue. In *Emhart Industries, Inc.*, the court found that although there was a delay in filing reexamination, that delay was the fault of the patentee in postponing needed discovery regarding the prior art. *Emhart Indus., Inc.*, 1987 WL 6314, at *3 ("Whatever plaintiff's reasons were for postponing these depositions, plaintiff will not now be heard to object to defendant's motion for stay on the grounds that too much time has passed since the commencement of this litigation.").

With regard to the other authority cited by 3M, in no instance was the delay between the commencement of the suit and the request for reexamination nearly as long as in this case. *See Tap Pharm. Prods., Inc.*, 2004 WL 422697, at *1 (reexamination requests were filed before the lawsuit began); *Ralph Gonnocci Revocable Living Trust*, 68 U.S.P.Q.2d at 1756 (request for reexamination filed within two months of the defendant's counsel's notice of appearance, and within eight months of commencement of suit); *Robert H. Harris Co.*, 1991 WL 217666, at *4 (request for reexamination filed within one year of commencement of suit); *Loffland Bros. Co.*, 1985 WL 1483, at *1 (request for reexamination filed within one year of commencement of suit); *Gioello Enterprises Ltd. v. Mattel, Inc.*, 2001 WL 125430, at *1 (D.Del. Jan. 29, 2001) (request for reexamination filed within 18 months of commencement of suit); *Grayling Indus., Inc.*, 1991 WL 236196, at *1 (reexamination request filed within two years of commencement of suit). [FN13]

> FN13. It is unclear in the *Softview Computer* decision, also relied upon by 3M, how much time elapsed between the commencement of suit and the reexamination request. *Softview Computer Prods. Corp.*, 2000 WL 1134471, at *1.

3M seeks to justify its delay in filing for reexamination by arguing there was a discovery stay in place as to validity that was "implicitly" lifted on March 11, 2003. Middleton counters by stating that, in the first place, the prior art upon which 3M based its request for reexamination was not the result of any discovery efforts engaged in by 3M and that 3M has not taken a single deposition on the subject prior art after such art was identified. Middleton asserts that 3M could have filed for reexamination at the PTO at any time, notwithstanding any discovery stay imposed by a district court. Finally, even if 3M was somehow impeded by a discovery stay, it still took 3M over a year after the stay was "implicitly" lifted to file its reexamination request. Middleton contends that under the circumstances of the present case, a one-year delay is inexcusable, and 3M should not be allowed to benefit from its delay.

Middleton seemingly misses the point in arguing 3M's delay warrants denial of the motion to stay. More important than when the reexamination application was made was the purpose behind said application. Thus, instead of looking solely at when the application was made with regard to the pending litigation, the Court looks at whether the petition for reexamination was made with a dilatory purpose. *See Grayling Indus., Inc.*, 1991 WL 236196, at *2-3; *Emhart Indus., Inc.*, 1987 WL 6314, at *3. While the timing of the application is relevant in making this determination, the Court also looks to the proffered reasons for the delay. *See Ralph Gonnocci Revocable Living Trust*, 68 U.S.P.Q.2d at 1758 ("Plaintiff may be correct that [defendant] did not act swiftly in seeking reexamination. Nothing in the record, however, indicates when [defendant] became aware of the prior art which is the basis for his request for reexamination.... Thus the Court cannot conclude that [defendant] unnecessarily delayed seeking a reexamination or that he is doing so now to stall this litigation."); *Grayling Indus., Inc.*, 1991 WL 236196, at *3 (finding that "although it is not clear that Plaintiffs had good reason for the delay in petitioning the PTO for reexamination, neither has Defendant shown such egregiously dilatory conduct as would justify short-circuiting the reexamination procedure now that Plaintiffs have invoked it"). Moreover, if "the Court finds that the benefits of granting a stay in the present proceedings outweigh the burdens, it need not decide whether the defendant could actually have filed its request at an earlier date." *Emhart Indus., Inc.*, 1987 WL 6314, at *3.

*8 In the present action, Middleton has presented no evidence, beyond pointing out that one of the prior art references asserted by 3M was its own patent, that indicates 3M had knowledge of the prior art and could have made the request for reexamination much earlier. Due to the stay of discovery on issues related to the validity issue, 3M was not actively pursuing this issue. [FN14] Significantly, 3M had won a judgment of non-infringement on two different occasions in the Northern District of Illinois. Accordingly, 3M may have had little reason to pursue the issue of validity until the stay on discovery was lifted. 3M also argues that under the last decision

from the Federal Circuit, the construction of the claims at issue was significantly broadened.

> FN14. Middleton argues that 3M did not have its hands tied by the Illinois court but instead put all its eggs into the infringement basket, holding in abeyance any argument on validity even though 3M has alleged validity from the beginning.

The record indicates it was not until this decision, and the subsequent course of the proceeding, that 3M began to actively pursue the validity issue. In May 2003, 3M received information pursuant to discovery that was relevant to this issue. Based on this information, 3M was able to gather additional information. Upon determining the validity of the '514 patent was an issue, 3M drafted the reexamination application, notified the Court, submitted a motion for summary judgment on validity, and, as soon as the reexamination was granted, moved for a stay. The Court finds it is not unreasonable under all of the unique circumstances of this case that it took 3M nearly a year from this time to file for reexamination, particularly in light of the numerous prior art references discovered, both domestic and foreign.

The Court finds that any delay in filing for reexamination is not cause to deny the motion to stay. While 3M may be guilty of focusing too much attention on the infringement issue, it was led on that course by the proceedings in the action. As soon as validity became a very real issue, 3M did not unduly delay in moving for reexamination. Moreover, there is no evidence that 3M has moved for a stay solely for a dilatory purpose beyond Middleton's argument to the contrary.

D. Prejudice to Middleton

Pursuant to section 318 of the Patent Statute, a court is not to issue a stay if it "would not serve the interests of justice." 35 U.S.C. § 318. Middleton contends that because of the prejudice it would incur should a stay be granted, such interests would not be served. When Middleton first filed suit against 3M, the patent in suit had more than a decade of useful life remaining, whereas now it is due to expire in less than three years. If 3M's proposed stay is granted, Middleton claims that it is likely that there will be no life remaining in the patent in suit in the event this matter is revived following reexamination; however, this fact alone is not sufficient to deny the motion to stay. *See* Tap Pharm. Prods., Inc., 2004 WL 422697, at *1 (dismissing plaintiff's argument that patent may expire thereby depriving them of any injunctive remedy because patent may still expire before trial is completed).

***9** 3M answers by stating that monetary compensation is sufficient to remedy infringement. Middleton disagrees and asserts that while it has no intention of commercializing the '514 patent, it would be deprived of its right to exclude others under the patent, stating that 3M's position would be tantamount to a compulsory license for using the patented invention. The Federal Circuit has found this to be an inadequate remedy for infringement. *See, e.g.*, Reebok Int'l, Ltd. v. Baker, Inc., 32 F.3d 1552, 1557 (Fed.Cir.1994); Hybritech Inc. v. Abbott Lab., 849 F.2d 1446, 1456-57 (Fed.Cir.1988). According to Middleton, because it stands to lose its ultimate remedy for patent infringement in the event 3M's proposed stay becomes a reality, Middleton will be severely prejudiced by such a stay, and this warrants denial of 3M's motion.

At present Middleton is not, however, selling or marketing products under its patent. Indeed, it has never done so and thus has no market to protect. Under similar circumstances, a district court found "money damages is an adequate remedy for any delay in redress" where the patentee was not "selling or actively licensing goods or services related to" the patent in suit. Gioello Enters, Ltd., 2001 WL 126350, at *2; *see also* Emhart Indus., Inc., 1987 WL 6314, at *2 (finding that "notwithstanding plaintiff's argument that monetary damage will not compensate for its losses, this *is* a suit for money damages and plaintiff has never sought preliminary injunctive relief from the Court").

Middleton is not currently selling products related to the patent in issue and would be entitled to any money damages if infringement is ultimately found. Ultimately, the Court finds this is sufficient to protect Middleton from suffering any undue prejudice or a clear tactical disadvantage. Should the action proceed to trial following reexamination, the Court may still order appropriate injunctive relief. In addition, Middleton would be entitled to money damages if proven, and there is no immediate danger of not being able to collect said damages from 3M.

E. Alternatively, Granting Stay Solely on Issues Before the PTO

In the alternative, if the Court issues a stay in light of the reexamination, Middleton urges that the stay be

limited to those issues pending before the PTO as part of the reexamination proceedings, i.e., anticipation and obviousness. Thus, the issues of infringement, willfulness, damages, and inequitable conduct would continue before the Court under Middleton's plan. Under this proposal, any judgment would not become final until the PTO has ruled on the reexamination and the parties' appeal rights have been exhausted unless the Court makes the judgment final as to those issues tried, [FN15] thereby entitling the parties to appeal the judgment immediately.

FN15. *See* Fed.R.Civ.P. 54(b).

As concerns the issue of validity, 3M's request was for a reexamination proceeding pursuant to Chapter 30 of the Patent Statute. Pursuant to section 315 of the Patent Statute,

> ***10** A third party requester whose request for an *inter partes* reexamination results in an order under section 313 is estopped from asserting at a later time, in any civil action arising in whole or in part under section 1338 of title 28, the invalidity of any claim finally determined to be valid and patentable on any ground which the third party requester raised or could have raised during the *inter partes* reexamination proceeding.

35 U.S.C. § 315(c). In other words, in the event the PTO finds the subject claims patentable, 3M would be estopped from returning to court to re-argue validity of those claims. Therefore, Middleton contends that staying only those issues before the PTO would be a practical solution that would provide Middleton with more timely relief on the remaining issues.

The PTO's reexamination could, however, affect more than just the validity issues before the Court. Indeed, a PTO decision that the '514 Patent is invalid could render moot the issues of validity *and* infringement. *See Gioello Enters. Ltd.*, 2001 WL 125340, at *1 (finding the PTO's decision could render moot the issues of non-infringement and invalidity before the court in pending motions for summary judgment); *ASCII Corp. v. STD Entm't USA, Inc.*, 844 F.Supp. 1378, 1380-81 (N.D.Cal.1994) (finding stay was justified because if claims were cancelled in reexamination then the need to try the infringement issue would be eliminated); *Loffland Bros. Co.*, 1985 WL 1483, at *2 ("The reexamination procedure has the potential to eliminate trial on the issue of patent infringement, should all of the patent's claims be cancelled.") "In addition, if a final decision of unpatentability means the patent was void *ab initio*, then damages would also be precluded." *Standard Havens Prods., Inc.*, 1993 WL 172432, at *1. The issues of inequitable conduct and willfulness may not be impacted by the PTO's determination, *see Enprotech Corp.*, 1990 WL 37217, at *1 (finding reexamination would not affect the inequitable conduct claim at issue), though to only proceed on these two issues would not serve the interests of justice. Therefore, the Court finds it would not be appropriate to stay only a portion of the pending issues.

CONCLUSION

For the foregoing reasons, the Court hereby grants Defendant's Motion to Stay the Proceedings Pending Reexamination of U.S. Patent No. 4,944,514 by the Patent and Trademark Office (Clerk's No. 170). The Court finds a high likelihood that results of the PTO's reexamination would have a dramatic effect on the issues before the Court, up to and including dismissal of the entire action if the patent claims are found to be unpatentable. In any event, the Court will benefit from the PTO's expertise and determination on reexamination, and Middleton will not be unduly prejudiced by the stay. Thus, under the unique circumstances of this case the Court finds the benefits of issuing the stay outweigh the arguments made by Middleton in resistance to the motion.

***11** IT IS SO ORDERED.

Motions, Pleadings and Filings **(Back to top)**

- 2004 WL 2723872 (Trial Motion, Memorandum and Affidavit) Defendant's Reply Brief in Support of Its Expedited Motion to Stay Pending Reexamination of U.S. Patent No. 4,944,514 by the Patent and Trademark Office (Aug. 11, 2004)

- 2004 WL 2723870 (Trial Motion, Memorandum and Affidavit) Defendant's Memorandum in Support of Its Expedited Motion to Stay Pending Reexamination of U.S. Patent No. 4,944,514 by the Patent and Trademark Office (Jul. 30, 2004)

- 2004 WL 2723863 (Trial Motion, Memorandum and Affidavit) 3M's Reply to Middleton's Opposition to 3M's Motions for Summary Judgment of Non-Infringement (Jun. 25, 2004)

- 2004 WL 2723866 (Trial Motion, Memorandum and Affidavit) 3M's Reply to Middleton's Opposition to 3M's Motions for Summary Judgment on Anticipation (Jun. 25, 2004)

• 2004 WL 2723868 (Trial Motion, Memorandum and Affidavit) 3M's Response to Middleton's Statement of Additional Facts (Jun. 25, 2004)

• 2004 WL 2723858 (Trial Motion, Memorandum and Affidavit) Defendant's Memorandum in Support of its Motion for Summary Judgment on 3M's Third Affirmative Defense: Invalidity of Claims 4, 5, 6, and 7 of U.S. Patent No. 4,944,514. (Jun. 14, 2004)

• 2004 WL 2723860 (Trial Motion, Memorandum and Affidavit) Defendant's Memorandum in Support of Its Motion for Summary Judgment of No Literal Infringement or Infringement Under the Doctrine of Equivalents of Claims 6 and 7 of U.S. Patent No. 4,944,514. (Jun. 14, 2004)

• 2004 WL 2723856 (Trial Pleading) Middleton's Answer to 3M's Amended Counterclaim (Feb. 12, 2004)

• 2003 WL 23908557 (Trial Motion, Memorandum and Affidavit) Middleton, Inc.'s Summary Judgment Reply (Dec. 19, 2003)

• 2003 WL 23908561 (Trial Motion, Memorandum and Affidavit) Middleton, Inc.'s Response to Defendant 3M Company's Statement of Additional Facts That Preclude Summary Judgment (Dec. 19, 2003)

• 2003 WL 23908548 (Trial Motion, Memorandum and Affidavit) 3M's Brief in Opposition to Middleton's Renewed Motion for Summary Judgment of Direct, Literal Infringement of Claim 4 of the '514 Patent (Dec. 03, 2003)

• 2003 WL 23908552 (Trial Motion, Memorandum and Affidavit) 3M's Response to Middleton's Rule 56.1(a) Statement in Support of Middleton's Renewed Motion for Summary Judgment of Direct, Literal Infringement of Claim 4 of the '514 Patent and Statment of Additional Facts in Support of its Opposition to Summary Judgment. (Dec. 03, 2003)

• 2003 WL 23908545 (Trial Motion, Memorandum and Affidavit) Middleton's Opposition to Defendant 3M's Motion to Strike Plaintiff's Motion for Summary Judgment (Nov. 07, 2003)

• 2003 WL 23908542 (Trial Motion, Memorandum and Affidavit) Defendant 3M's Memorandum in Support of Its Motion to Strike Plaintiff's Motion for Summary Judgment (Nov. 03, 2003)

• 2003 WL 23908537 (Trial Motion, Memorandum and Affidavit) Joint Proposed Scheduling Order and Memorandum in Support (Oct. 31, 2003)

• 2003 WL 23908531 (Trial Motion, Memorandum and Affidavit) Memorandum in Support of Middleton's Renewed Motion for Summary Judgment of Direct, Literal Infringement of Claim 4 of the '514 Patent (Oct. 27, 2003)

• 4:03cv40493 (Docket) (Sep. 04, 2003)

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